MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

DR. WILENSKY: Let's get started. Helaine?

MS. FINGOLD: Good morning. This morning and a little this afternoon we're going to be talking about mechanisms for improving and safeguarding quality under Medicare. We're going to start with a panel on survey and certification issues. We want to thank our three panelists for coming this morning and being our first presenters.

We have Rachel Block who's with the Health Care Financing Administration. Rachel is the deputy director for the Center for Medicaid and State Operations that oversees Medicaid survey and certification, CHIP, and insurance reforms under HIPA, just to name some of the many things that she deals with.

Kathleen Smail is manager of health care, licensure, and certification with the Oregon health division. Administers the state licensure and Medicare certification process for non-long term care providers and suppliers in Oregon. She is here speaking on behalf of the Association of Health Facility Survey Agencies.

Lastly, we have Margaret VanAmringe who's with

JCAHO, the Joint Commission on Accreditation of Health Care Organizations which does accreditation of many types of facilities and has deemed status for a number of those facilities for Medicare certification.

So we'll start with Rachel, and thank you and welcome.

MS. BLOCK: Thank you very much. It's a pleasure to be with you today. If you found a common theme in terms of the description of what the Center for Medicaid and State Operations does and why I am here is because we are responsible within HCFA for overseeing the states' activities with regard to survey and certification. CMSO is responsible for all of the HCFA programs that are administered by or through states. It is, I think, unique in that it is a function that is specific to the administration of the Medicare program but where states are really the mechanism by which the Medicare requirements are assessed and evaluated.

I'd like to start with just a very brief introductory or contextual comment. There are, obviously, a number of ways in which HCFA's authorities and our

activities touch on and relate to the quality of care that are provided to Medicare beneficiaries. We obviously develop and establish the conditions of participation for a wide array of providers. Jeff Kang from the Office of Clinical Standards and Quality is actually directly responsible for that function.

In addition, Jeff will be speaking to you more specifically later about the role of the peer review organizations as that fits into our larger quality context. I'm not sure if it's part of his prepared remarks, but HCFA is now embarking in a much more proactive way to articulate our view of ourselves as a purchaser in concert with other purchasers in the development of performance measures as it relates to health care in explicit partnership with others in the public and private sector.

So the survey and cert process then is really just one element in a number of different tools and ways in which HCFA in fact attempts to articulate the quality standards and to ensure that providers are meeting those standards. So the survey and cert process really fits into that larger system and it really is, in a way, the traditional, the

foundation if you will, for our approach to quality, which is to ensure that providers serving Medicare and, both indirectly and directly Medicaid beneficiaries, are complying with the established conditions of participation, which in large part articulate a broad set of standards regarding the health and safety of the health care that is provided to beneficiaries in those settings.

For nursing homes, as I'm sure most of you know, our mandate is broader. We are in fact responsible for the quality standards and the enforcement and compliance of nursing homes for all nursing home residents, not just those whose care is paid for through Medicare and Medicaid. In that sense it approaches something more like a public health assurance function as opposed to purely a regulatory function associated with Medicare and Medicaid.

As I'm sure the other two speakers will also touch on, and as I'm sure you know, for hospitals and many other classes of facilities and providers there is a tradition in which private accrediting bodies have played an important role as a proxy or an extension of our overall system for ensuring that providers are meeting Medicare's quality

standards.

One of the topics I was asked to touch on briefly -- and I will be brief because Jeff will be speaking to you more about the function of the PROS -- is how do you distinguish the role of survey and certification from the role of the PROs, and I believe actually that the other speakers might touch on this topic as well. As I indicated at the beginning, the primary distinction is that the survey and certification process is a regulatory process. The goal here is to ensure that quality health care is being delivered.

It does not have as its purpose a focus on quality improvement and some of the other related functions which are important to a comprehensive approach to quality, but which are simply not the core business of what survey and cert has been about. In fact, some of our current initiatives are really focusing on trying to be more clear about the distinction between that regulatory function and the quality improvement function, and hope we'll ultimately make the activities that we sponsor under those different rubrics more effective in terms of meeting their respective

goals.

As I also indicated, this is a unique function for Medicare in that it is conducted through states. That has certain very specific advantages I think from my point of view, not the least of which is that states really perform a number of other important licensing and certification processes so there is a certain efficiency associated with this. Also states, obviously, have an accountability to residents at a local level which has, I think, proven to be relatively effective in terms of their ability to conduct these activities on behalf of the Medicare program.

But it also results in some inconsistencies in terms of the approaches which are taken, the amount of resources which are devoted, and also the strength or weakness of the overall regulatory infrastructure that might be in place in a given area. All of these inconsistencies have been cited by HCFA, by the General Accounting Office, and by the Office of Inspector General, in particular recently in a series of reports focusing largely on issues relating to nursing homes which I'm sure you are all familiar with, and also more recently, with regard to

hospitals.

So the issue of consistency, the strength of the approach that we take in terms of the enforcement of standards, all of these have now been really much more at the forefront of our interest and activities in the last couple of years.

We've taken a number of steps to strengthen the enforcement process. Again, primarily focusing here on nursing homes, but where some of these approaches will begin to spill over I think into some of the activities that we undertake for other provider categories. In particular, we have been looking at improving, strengthening the penalties that are associated with violations of standards. We have been looking at issues relating to how can those standards be clearer to providers.

And we have also strengthened, as the first step in our overall approach to this process, our direction to states in terms of our expectations for how the survey process would be conducted in such a way that we hope it will be more effective, both in detecting problems in nursing homes, but also ultimately to ensure that we can say

with confidence that there is a high quality of care being provided, since that really is what we hope will be the result out in the real world.

We have also implemented a number of policies and procedures to ensure the accountability of accrediting bodies. I'm sure Margaret will touch on the hospital oversight plan that we have been working on in response to the recent report from the OIG. In particular here, and also to a certain degree in the nursing home area, one of the key issues that will be at the center of attention is how we conduct the review of the survey process itself.

The federal government has as one feature of its activities something that we call oversight surveys. We conduct those oversight surveys in conjunction with the accrediting bodies. We conduct those oversight surveys in conjunction with the states. There are different methods by which those oversight surveys can be conducted, and there is a big debate that will soon be emerging and the GAO's next report on the nursing home side will touch on this issue about which types of oversight surveys are better, which are most likely to achieve the result.

In general though, we have beefed up our resources devoted to oversight surveys and again, particularly on the nursing home side, we will very shortly be releasing some data to show what we have accomplished there and how we intend to use that as part of our broader nursing home initiative.

We have also, in addition to directing additional resources to our regional offices for these purposes, we have committed specific additional resources to the states through the survey budget. I don't know if many of you realize that the budget for survey and certification had for many years been held relatively constant and just clearly did not provide a sufficient level of funding to conduct the frequency and type of activity that was either expected by law or consistent with what we thought were appropriate standards of quality, to assure quality in those facilities.

We have gradually increased the resources specifically devoted to nursing homes. We have in our 2000 and also our 2001 budgets, requested additional resources in selected other areas as well. So the budget is a very important component to this and one which I think states

appropriately point to when we go and ask them to do more things, or to do a better job in certain areas, and we have made an effort to address that through the budget process.

Finally, one of the other areas that is really critical to our ability to answer our questions and the public's questions about what is going on with respect to the process by which quality is ensured is, do we have a basic data collection and reporting system in place to actually collect key information that is derived from the survey process? That includes both the actual findings of surveys as well as data regarding complaints and other things that are really key to be able to determine where the problems are, and also where the problems are not.

We have focused a lot of attention, frankly, on really basic issues like how timely is the submission of survey data? It may not seem like a big deal, but as you get into a cumulative pattern where survey results are not reported on a timely basis -- and that includes, by the way, our own federal surveyors who are out conducting those oversight surveys that I mentioned -- it becomes an important gap in terms of your ability to ensure

accountability in the system. So that's another area and I expect that we will be developing some specific performance measures for states in that area.

That's a really brief overview of some of the more traditional methods, processes, procedures that we currently use and areas where we have put more emphasis. I'd like to touch though briefly on a couple of areas that really look more to the future although they are things that we're starting to do now, but I think represent some pretty exciting developments in terms of where we would like to go.

The first is, under the Government Performance Results Act, we along with all the other federal agencies are expected to measure and report on actual outcome measures. We have several in the survey and cert area. I won't go into all the details of that, but they really focus in large part on actual health outcomes of beneficiaries. So we, through the survey and cert process intend to hold ourselves accountable for key measures in that area.

I mentioned the overall funding for the survey budget. In addition to that, the actual method by which the survey budget has been constructed just has to be really

scrapped and reinvented. It is no longer a viable method to construct either an effective budgeting system or a method to really ensure that the appropriate resources are being developed. So that's another, I think very exciting and important development for the future that we're starting to work on now.

I know you're all aware of the minimum data set. We are using the minimum data set now to incorporate quality indicators into the nursing home survey process, and shortly thereafter we will be using the same basic approach to introduce quality indicators into the home health certification process. This is, obviously, going to make the whole process for survey and certification more data driven, which I think we all would agree is a better way to go than just measuring structure and processes of care.

And also to be available on site, literally, through hand-held PC laptops or Palm Pilots or what have you, that the surveyors are now increasingly using so that they can pinpoint very specific patient care and patient outcome related issues while they're on site conducting the survey. We think this will be a significant improvement in

the survey process.

Consumer education is a very important component of our current strategies. I'm not sure that they have really ever received so much emphasis. And of course, all that data can be very helpful if constructed in a way that is helpful to consumers. In particular, we have put on our web site the results of nursing home surveys which is the most popular area on HCFA's web site right now. I hope that some of you may have looked at it.

Finally, one new and potentially interesting area for us to be focusing on, at least indirectly through the survey process but it could have a huge impact, is the emerging financial status of many of the key sectors of health care that we are responsible for ensuring quality within.

I am sure you know that we have major concerns about the bankruptcy of one, and now today another major nursing home chain. There have been several smaller chains which have not achieved national attention but which we have been working in those states to ensure that quality continues to be provided while the financial restructuring

or whatever other issues are being worked out are occurring. We have had, frankly, extraordinary cooperation from the states under circumstances that make all of us concerned about our ability to monitor the quality of care in those facilities. But we believe that we have a pretty effective network out there to monitor those issues.

That is just one additional example of how the survey and cert process has been used to deal with emerging issues, and I would be happy to answer questions as we continue with the rest of the session. Thank you.

DR. WILENSKY: Thank you. Kathleen?

MS. SMAIL: Good morning. Thank you for the opportunity to speak to you today about issues of Medicare survey and certification. As Helaine said, I'm representing the Association of Health Facility Survey Agencies. My discussion today will focus on the roles and relationships of state survey agencies, peer review organizations, and the Health Care Financing Administration; the PROs and HCFA as we common refer to them. I was asked to address certain topics so they will be woven into my discussion this morning.

I should also mention that I'm speaking from the perspective of one of the five states in the country that have totally separate state survey agencies for non-long term and long term care. So my perspective, of course, is going to be from the non-long term care side because that's where I work.

State agencies, PROs, and accrediting organizations share a common goal of ensuring high quality health care. While there are similarities among these entities, there are also some very important differences. The roles of state agencies carrying out Medicare certification processes, and the PROs conducting quality improvement projects are different and complementary. State agencies provide regulatory oversight and during surveys we review the entire organization and the delivery of care. We actually watch care being delivered.

The state agencies focus on ensuring that systems are in place, as Rachel said, to provide for safe patient care in every aspect. I should just throw in a little illustration here which I mentioned to someone earlier, that it's very important to look at patient outcomes, but it's

also important to see that systems are in place. Because if you don't have the system of a stop sign at a busy intersection, it doesn't do much good to look at the outcomes because you need to prevent some of those outcomes.

Reviews conducted by PROs are in depth, but limited in scope and focus on achieving good patient outcomes. The PROs conduct clinical reviews, carry out research, review medical practices, and make recommendations including specific treatment protocols for improving care. While PROs do investigate some complaints, those generally take place through the mail requesting a medical record or a number of medical records, and they usually involve patients who are Medicare beneficiaries.

State agencies, however, conduct on-site complaint investigations regardless of patients payment sources. State agencies also can cite deficiencies and require providers to submit plans of correction.

It's also important to recognize the role that renal networks have in the Medicare system. In many ways, the networks function like the PROs in working with dialysis facilities. With the goal of improving the quality of care

for Medicare beneficiaries, they conduct studies of the adequacy and the effectiveness of dialysis by reviewing patients' outcomes and laboratory values. They work to improve data reporting and the validity of that reporting.

The role of the networks in complaint investigations is less clear. Network staff act as facilitators and mediators to resolve complaints and grievances between patients and facilities. Sometimes the first action of the network is to refer the complaint or grievance back to the facility for internal investigation. Patients have told surveyors that they feel afraid to complain because they're confidentiality might not be maintained, and as you know they're very dependent on their caregivers in a dialysis facility.

In Oregon, it's been our experience that rarely does the network refer complaints to the state agency. State agencies protect the identity of complainants and investigate the complaints directly. Sometimes problems may arise from the fact that sitting on a network's medical review board or advisory board may be employees of the dialysis facility or corporation against which a complaint

is lodged.

Relationships between state agencies and PROs vary, no doubt, from state to state. In Oregon, the health division has an excellent working relationship with our PRO, the Oregon Medical Professional Review Organization, or OMPRO. We've participated in a number of cooperative projects to improve patient care, and we meet with them at least annually. We look forward, for example, in the next fiscal year to assisting them in their project of working on Medicare fraud reduction.

We are also working to establish a similar relationship with the Northwest Renal Network and we hope to be able to accomplish that. We believe that a strong cooperative relationship between state agencies, PROs, and networks, recognized and supported by HCFA, can be very effective at improving health care quality.

Accrediting organizations have the ability to be a very effective force in partnership with PROs and state agencies. As in the case of the PROs, their role is very different from but complementary to state agency roles. Recognizing that collaboration is important, state agencies

and accrediting organizations such as the Joint Commission on Accreditation of Health Care Organizations, have increased the sharing of information.

I'm sure that you're familiar with the recent report from the Office of the Inspector General describing the approach of accrediting organizations as collegial. This is an important and valuable approach. Since accrediting organizations operate at a national level, they have a unique opportunity to serve as educators, and they can share with the providers across the country various best practices. Because of the prestige accorded to accrediting organizations, providers may be very receptive to suggestions and recommendations made by the surveyors during those accreditation surveys.

In many cases, the accreditation process has accomplished the goal of improving the quality of health care. However, we are concerned about several problems which are inherent in the process of deemed status. First, there's the disjunctive relationship between the Medicare regulations and the accrediting organization standards. I'm not going to use that fruit cliche, but it is like two kinds

of fruit. Compliance with one does not guarantee compliance with the other.

In a hospital program, for example, HCFA has recognized this and it has modeled the requirements in the proposed revision of the hospital conditions so that they will be more like the Joint Commission's standards. The Joint Commission, however, revises its standards on a fairly frequent basis and the result is that once again the standards and the federal regulations will be out of sync.

Further, the Joint Commission is not the only accrediting organization for hospitals. The American Osteopathic Association also accredits hospitals and they have their own standards. We believe that federal regulations should comprise the fundamental standards with which providers must comply and that accrediting standards should serve in addition to those regulations.

Second, there are problems with, for example, hospital validation surveys. As you've heard, HCFA does select a number of look-behind, follow-up surveys and validation surveys are one type. In that case, hospitals which have just been accredited or had their accreditation

survey are inspected by state surveyors who are surveying for compliance with the Medicare regulation and then at some point results are evaluated. Surveyors have found, however, that hospital staff are not familiar with the Medicare regulations and in some cases, at least in Oregon, we've been told that those regulations don't apply to us because we're accredited.

The fact is that the findings of the validation surveys seem to carry little weight. Deficiencies identified by state surveyors and communicated to hospital administrators, but no plans of correction are required for those deficiencies and standard level deficiencies need not be corrected.

Again, we are concerned about the use of deemed status if it is based on the premise of reduced cost to HCFA and ultimately to the taxpayers. Reducing the funding for state agency survey coverage and allowing accreditation to substitute for that activity does seem on the surface to save money.

However, providers must pay for their accrediting surveys and they also have to pay the cost of the staff who

spend months preparing for that. It's our understanding that these expenditures are then listed in annual cost reports and that part of those costs are reimbursed by HCFA. Since accreditation surveys can be considerably more than state agency surveys, the end result is that deemed status may actually wind up costing as much, if not more.

In federal fiscal year 1991, state agencies were funded to do 100 percent survey coverage of providers, but since that time funds, as you've heard from Rachel, have been reallocated to support the long term care survey program. In the last federal fiscal year, survey coverage level for non-long term care providers other than home health have been reduced to 10 percent.

What that means is that dialysis facilities, non-accredited hospitals, ambulatory surgery centers, et cetera, are surveyed, on average, once every 10 years. There are plans in the current fiscal year 2000 to increase that a little bit to 11 percent, and 15 percent for dialysis facilities, but this is clearly not sufficient.

It's unlikely, for example, if we don't show up very often that the employees will be at all familiar with

the Medicare requirements. While long term care is very, very important, to increase regulatory oversight in protection for Medicare beneficiaries in nursing homes at the expense, for example, of the vulnerable, medically fragile Medicare beneficiaries in dialysis facilities is not a safe policy. We have found that the number of complaints, and I would say substantiated complaints, and the number of condition level deficiencies has increased significantly during these years.

Finally, there are other important differences between accrediting organizations and state agencies. State agencies are local. We meet with the providers to make them familiar with Medicare regulations. We carry out timely, on-site complaint investigations. And our surveys are essentially unannounced. Backed up by the authority of statute and regulation, we have the power of enforcement.

For these reasons, we do not recommend extending deemed status to other providers and suppliers. Rather, we recommend supporting and strengthening the responsibilities of state agencies, PROs, and accrediting organizations. As in any regulation, some are more effective than others. The

regulations must apply equally to all sizes and complexities of provider organizations and so they contain minimum standards. The example I always give is, in Oregon we have one very rural 12-bed hospital. We also have a very large level one trauma hospital in Portland and they both have to comply to the same set of regulations. So they have to fit.

Most of the Medicare conditions are very effective. There are some conditions that are very generally and could use more specificity. For example, the federal regulation for dialysis facilities dealing with physical environment has very, very specific detailed requirements for water quality which it has incorporated from the Association for the Advancement of Medical Instrumentation.

However, it contains very general language about preparedness for medical emergencies, and during surveys in Oregon this last fiscal year we have found some facilities to be woefully unprepared for medical emergencies, including having empty oxygen tanks, an emergency tray with only Benadryl on it, a defibrillator where the paddles were locked up in someone's office and we were told the reason

for that is because the staff didn't know how to operate a defibrillator, and an incomplete and ineffective system for caring for patients experiencing cardiac arrest.

Now AHFSA, or the Association of Health Facility Survey Agencies has worked in the past, and continues to work and be committed to working with HCFA in technically advisory groups to revise regulations, set policy, and so forth.

The enforcement process for non-long term care is different than that for long term care which is quite sophisticated. We can cite deficiencies and require plans of correction, or we can initiate termination actions. There are no intermediate sanctions such as civil penalties or limiting admissions. But we haven't taken a position on whether more formal enforcement needs to occur. More frequent surveys might preclude the need for intermediate sanctions.

Consumers and patients can benefit from the survey and certification process in a number of ways. During Medicare surveys, the surveyors interview patients. In home

health and hospice, for example, the surveyors go into the patient's home and speak with them privately at the conclusion of the delivery of care.

Also, every state has a toll-free hotline for home health patients to call, ask questions, and talk about their care. State agencies also receive complaints from patients' families and other consumers, and that's another way in which individuals can be heard. We've also invited consumers in the past, and will continue to do so, to work with us when we revise the rules, and they have can a voice at the table.

We have not found issues of privacy and confidentiality to really create a barrier in the survey process. There are a couple of federal regulations that set the foundation for that; one which requires the providers to make available to the surveyors whatever information they need to conduct the survey, whether it's medical record information, or medical staff bylaws, or whatever it is. The federal regulation also preclude the state survey agencies from releasing the identities of individuals.

We do make publicly available general survey

information such as the deficiencies that have been cited and the plans of correction. But identities of individuals are not publicly releasable.

Finally, in conclusion, the assurance of safe, high quality health care relies on maintaining a strong, balanced process. If you want to think of that as a three-legged stool that would fit, with the state survey agencies being one leg, the accrediting organizations another, and the peer review organizations and the renal networks the third leg.

Clinical studies, education, and regulatory oversight are necessary parts of that approach. These three organizations must work collaboratively and productively in partnership with each other and with HCFA, and the Association of Health Facility Survey Agencies strongly endorses that philosophy.

I'll be very happy to answer any questions at the conclusion of my colleague's presentation.

DR. WILENSKY: Margaret?

MS. VanAMRINGE: Thank you. Because I'm speaking from the perspective of the Joint Commission, let me just

mention a moment of context here. We now accredit nearly 20,000 organizations, and they include such health care entities as hospitals, home care facilities, nursing homes, laboratories, hospices, behavioral health organizations, and managed care organizations. So we have a very full range on our plate.

In terms of deemed status, however, our deemed status is limited to hospitals, home care facilities, laboratories, ambulatory surgery centers, and hospices. We do hope when HCFA completes its regulations for Medicare+Choice deeming that we will receive deeming under that program as well.

Accreditation has played a significant role in the survey and certification process since the inception of the Medicare program. In 1965, the government viewed private sector accreditation as the gold standard for hospitals and incorporated the concept of deemed status into the Social Security Act, thus allowing accredited hospitals to be recognized as meeting federal quality of care standards. Over the years, the statute was expanded to include deeming for other types of health care providers that had quality of

care requirements or conditions of participation.

However, because of a drafting oversight in the 1980s, end-stage renal disease facilities were overlooked when deeming authority was consolidated in the statute. Further, it was not envisioned at that time that medical suppliers would have quality of care requirements for participation in Medicare, so no deeming authority was put forward for DME and other medical suppliers.

The construct of deemed status has proved itself to be a valuable one. I would like to stress, however, that the deemed status framework is one of partnership. It is not one of delegation of federal authority to the private sector. Deemed status is most effective when a strong collaborative effort exists between the government and private sector partners to reach mutual quality of care goals for Medicare beneficiaries.

Today's public-private deeming partnership has a strong infrastructure and significant potential to be even better, because it brings different but equally important strengths to the table. The combined product leads to an oversight system that is better than either partner could

perform alone. Let me provide a few salient examples of this.

The first is improved standard-setting. Certification provides the threshold requirements that each organization must meet before it can receive Medicare reimbursement. Accreditation standards go well beyond Medicare requirements because they are optimal achievable standards. They're also different from Medicare requirements because they are focused on performance, not on inputs.

Deeming provides a mechanism by which the Medicare program can avail itself of the most current, professionally recognized, and tested standards of care. This is an extremely important benefit of deemed status because changes in health care delivery are happening faster than the ability of HCFA to promulgate current health and safety requirements. In contrast to the government accreditation standards are continuously evaluated throughout the year and are updated annually to keep pace with the provision of state-of-the-art medical care.

Furthermore, new accreditation standards are

evidence based. They are field tested to ascertain their viability, their discernment capabilities, and their surveyability.

On the other hand, certification standards often can reflect very important and special public policy interests for specific federally-funded programs, such as special patient rights, or access to care, or access to certain health information. Private sector accreditors then have the opportunity to incorporate such requirements, as appropriate, into their accreditation programs and this is a very good thing.

Second, the deeming partnership extends the reach of survey and certification to thousands of additional health care organizations without having to rely upon the government appropriation process for more survey dollars. There is a double benefit here because in addition to holding down taxpayer costs, government recognition of accreditation also increases the absolute number of organizations which aspire to standards that go beyond Medicare's threshold. This is because deemed status recognition has been shown to be a very powerful incentive

for organizations to seek accreditation.

A third benefit is the ability of the accreditor to do provider education and to empower organizations to do continuous quality improvement. By contrast, the regulatory process does not lend itself to an educational role. The private sector brings to the partnership a cadre of surveyors who have the knowledge, skills, and opportunity to help those providers who need it to understand how they could do better and how to improve their performance.

It is not sufficient to tell an organization that it does not meet standards. There must be specific recommendations for what must be changed and a clear understanding of how to improve processes and achieve better patient health outcomes. Health care organizations view the consultative nature of accreditation as a major asset.

A fourth benefit is the ability of the partnership to use different leverage points to bring about change. It does this by using both voluntary and regulatory incentives. This may be among the most important points because each type of incentive has its own role in the oversight process. Kathleen has touched on this a bit so I

won't go into too much detail. But certainly concern over losing Medicare certification, and thereby reimbursement, is a very powerful incentive to make changes.

The regulatory approach is needed to weed out those organizations without the commitment or resources to meet threshold requirements. Accreditors can help bring these organizations to light and work with HCFA and the states to invoke enforcement. However, we should recognize that external incentives are generally short-lived ones. There is evidence that they last only as long as the threat is visible or that the gun is to the head.

Accreditation capitalizes on the internal incentives of health care professionals to meet state-of-the-art professionally recognized standards. Because most organizations take accreditation very seriously, they make significant and sustained strides in improvement when faced with accreditation recommendations. The net result is a continuous upper improvement of the mean performance of health care organizations.

I should also say we're moving in some new directions over the next couple of years in addition to what

we have been doing over the last five, which is really implementing our performance-based approach to quality monitoring. We now have an accreditation process improvement task force that started about a year ago and has been looking at ways to improve the survey process, and this will also be a benefit to Medicare beneficiaries.

We're looking at ways to improve our input from consumers into that survey process, to do more random, unannounced surveys, and to redirect the time that we spend on site in organizations to more high yield ways to look and find the kinds of problems that we know are often out there. I hope that this will prove very fruitful as these accreditation process improvements roll out over the next year or so.

We are also announcing the creation of a public advisory group which has been in the works for quite some time and hopefully they will have their first meeting later this year. That's another way to bring some more consumer input into our process.

Now Rachel and Kathleen have both mentioned the IG report so I won't go into the things that we are pursuing

under the workplan that we have with HCFA to implement many of the IG recommendations. But let me just say that I think they are all worthwhile recommendations in that report and we look forward to our work with HCFA on them.

But I would like to mention a couple of other things which I think are worth pursuing in the deemed status relationship. The first is more emphasis on increased data sharing. One of the most important aspects of the deeming partnership is the ability to share information about a provider's history. Pre-survey information about a health care provider can be a significant tool to help focus the time spent on site by surveyors.

Over the years there's been some sharing of complaint data and other survey findings between HCFA, the states, and accreditors. However, this is an area that can be significantly improved by more systematic assembly of data and exchange of this information on a facility-specific basis.

A very specific recommendation here is for the data sharing of OASIS information. Rachel mentioned that OASIS information will soon become a very important part of

the survey and certification program. The Joint Commission hopes that the same OASIS information will be made available to accreditors so that as part of our deeming relationship for home health agencies we can avail ourselves of the same very important continuous stream of facility-specific information.

This is an area, however, where concerns over patient confidentiality could prove to be a barrier, and we do not think it should be a barrier for several reasons. One, the Joint Commission has a long history of protecting patient-identifiable information. And secondly, systems can be put in place to make sure that information about specific individuals is de-identified.

Another area that I think is very important is to expand the statutory authority for the use of deeming to other providers and the suppliers such as ESRD facilities and DME suppliers. We also believe that there should be an increase in the budget for survey and certification to permit a more frequent survey cycle for non-long term care providers of care that are not accredited. We have made this point over the last three or four years, but we do

believe that Medicare beneficiaries that are receiving high risk services in non-accredited hospitals, surgery centers, and end-stage renal disease facilities, and they are not receiving the level of oversight in the survey and certification process that they should.

Another area that I think is important is to help accreditors in their quest to promote error reduction strategies in health care organizations in a penalty-free environment. Health care is a complex enterprise. It is highly dependent on human interventions and interactions. More information is needed about what goes wrong and why, and accreditors do have the ability to help organizations make the system changes that are needed when problems occur.

Lastly, we believe that increased public accountability is important and we think that there can be some better linkages between HCFA web sites and Joint Commission performance reports that are currently on the web. We have information about the performance of individually accredited facilities; that's nearly 20,000 organizations. We look forward to ways to link with HCFA so that Medicare beneficiaries have more easy access to this

information.

Let me close in talking about the PROs for a moment because I think PROs are a very important part of the oversight fabric. They've already been mentioned quite extensively by Kathleen so I'll just highlight a couple of points that relate to how accreditors are working with the PROs.

We now work with them in several ways. First, the Joint Commission supports the appropriate use by hospitals of PRO studies. Credible data collection and analysis by PROs can form the basis of quality improvement initiatives that meet certain of the Joint Commission's accreditation standards for performance improvement.

Second, accreditors and PROs collaborate in the area of data-driven performance measurement. In 1997, the Joint Commission launched ORICS requirements for accredited organization. Under ORICS accredited organizations must report measurement data on a quarterly basis. These data can then be used for comparisons for other organizations and within the same organization over time.

Data integrity and standardization of data are key

elements to the success of ORICS. To this end, a number of PROs have chosen to become performance measurement systems listed with the Joint Commission as having the ability to collect and report ORICS data for hospitals.

Another area of collaboration is the development of measures themselves. The Joint Commission is in the process of developing core measures for accredited hospitals and we have recently formed a number of expert panels for selected medical conditions. We are very pleased to have experts from several PROs sitting on our core measurement panels. Further, when there is the overlap of interest we hope to use actual measures from the PROs sixth scope of work. The dialogue we've had with PROs on core measurement has been extremely fruitful and we think this has been a very positive development.

Lastly, to the extent PROs become involved with error reduction strategies, there should be coordination and data sharing with accreditors performing the same role.

In sum, there are many actors in the quality measurement improvement arena. The good news is that there is more than enough room for each to contribute greatly to

quality monitoring. Unfortunately, there's also the risk of unnecessary duplication of efforts and the possibility of lost opportunity to develop synergies between the parties. We're entering an era that calls for increased collaboration and we hope that we can do our part to help weave that better fabric with the states, with PROs, with HCFA, and all others that are interested in quality oversight.

Thank you.

DR. WILENSKY: Thank you. I'm going to open it up to the commissioners to either talk in general or comment in general about these issues, or to ask any of the three presenters specifically about issues they'd like to pursue.

DR. NEWHOUSE: This is specifically for Margaret, but any of the others, happy for you to address it. You mentioned as a priority the need for error reduction. I'm wondering about two somewhat separate issues. One, could you elaborate a bit on the institutional mechanism you see for reporting in a penalty-free environment? How would you do that?

Secondly, you mentioned an exchange of data, particularly on OASIS. But I'm wondering, if you set up a

mechanism that there was reporting of errors and there was kind of a freewheeling data exchange, do you see that that would also come back to HCFA and the state agencies? If so, would people be then reluctant to report?

MS. VanAMRINGE: Let me take maybe your last piece first, because I think there is reluctance to report now. We're seeing that all over.

The Joint Commission started the issue of error reduction back in about 1995 or '96, and we put forward a sentinel event policy at that time, which has changed substantially over the years. But what it has basically said is the structure is that we want to have information about when errors occur because if we don't have that information then we can't be sure that there have been the necessary analyses of problems completed and that there have been appropriate interventions made to make sure that those errors do not occur again.

We believe that there needs to be some change in federal law in order to have a more penalty-free environment. At this time there's a patchwork of state laws that deal with peer review and error reporting. This has

made it very difficult for the Joint Commission to have any centralized data repository on errors other than from states which have laws that are compatible with our error reduction policy. Let me give you an example.

In states where reporting an error to the Joint Commission would mean that the peer review statute has essentially lessened its coverage for that organization because it has shared the information with the accreditor, it can mean in a state that that information is now available to anyone who wants that. So it has essentially pierced the veil of that confidentiality. So in those states we're not receiving information.

However, our policy does state that when there's an error in those states that occurs, those organizations must do something about that sentinel event. When we go on site we will review their error collection policies and their root cause analyses that they are mandated to do by use for those sentinel events and make sure that they have actually implemented the changes that we want to have take place. But until there's some kind of federal statute that has a confidentiality provision for the root cause analysis

we will not see the kind of error reporting that we'd like to see nationally.

Now I think there's another piece to your question about sharing that data with regulators. Currently, we share any information with HCFA that they would like to have, but that information is also protected from redisclosure by the Medicare statute. I think there are issues there about what that redisclosure would be that would have to be looked at in any kind of infrastructure for data sharing.

But obviously, we are all for information collection. We believe that HCFA has a very important role to play here and we would support, as much as possible, a national scheme for error reporting that does this in a penalty-free environment but also, I would say promote and mandate the root cause analyses being completed and available for accreditors to review.

DR. NEWHOUSE: When you say a penalty-free environment, what would that mean institutionally? I understand it would be -- to what agency -- would this be an existing agency, or would it be a new agency?

MS. VanAMRINGE: We're only looking at it in the context of accreditors, because we'd like to see information reported to us so that we could do some oversight processes. I believe others are looking at it in terms of some kind of a national program, such as the IOM has been evaluating whether there should be some kind of another repository for that information. That is something which I think is beyond our particular province. As I said, there are many stakeholders in this and to the extent that information is shared without compromising the root cause analyses, we would support that.

DR. MYERS: Perhaps Rachel Block could address a couple issues I've been concerned about. One of the sticking points that always exist between those who regulate and those who are regulated are things like staffing ratios. I believe, and I'm not sure whether it was for SNF facilities or for others that in California recently a state law was passed that mandated specific staffing ratios. HCFA has talked for years about advancing quality and doing things differently, and so on and so forth, but I've never really heard HCFA declare itself on the issue of staffing

ratios. Has that changed?

MS. BLOCK: The only place that I'm aware that our current standards address staffing at all is on the nursing home side, and there are some fairly broad requirements about the adequacy of staffing. We are currently in the process of completing another leg in a rather extensive study in which we will be documenting whether we can draw a conclusion about staffing levels and the adequacy of staffing to the quality of care provided in nursing homes. Then from that I think we expect that we, the Congress, and the public will have an opportunity to discuss, based on those conclusions, what kinds of policies and other issues should play out once we have that study completed.

So I'm not today going to reveal a new HCFA position on that, but I do think that the study is going to be an important contribution to answering some of the questions that people have. But it will be specific to nursing homes. And I'm not aware of -- and I'm going to look to my colleagues -- that we have specific standards regarding staffing in other areas that go to the amounts or levels of staffing. There many out in the community who are

very interested in that topic though.

DR. MYERS: If I could have a follow-up question? HCFA has for years also, with respect to the hospital side, seemed very comfortable, at least outwardly, with deemed status. Yet for the nursing home side that's never been the case. Why is that?

MS. BLOCK: There may actually be commissioners here who could speak to that even better than I could because the last debate about deemed status occurred before I became involved in these issues. But I think that, fundamentally, the issue of the public accountability for care in nursing homes, the broad mandate that HCFA has to ensure quality for all nursing home residents independent, as I mentioned before, of whether they are receiving payment under Medicare or Medicaid, and the nature of the issues in nursing homes have led to a policy conclusion, at least to date, that deeming was not an appropriate mechanism to use for nursing homes. That a regulatory approach was the way that we would go.

But I'm not really in a position, Woody, to address the entire history of that. We published a report

to Congress last year which is literally this high [indicating] that addressed very extensive analysis of accrediting issues and I'd be happy to get you a copy of that if you would like to look at it.

DR. MYERS: I'll take the executive summary.

MS. BLOCK: We could do that.

DR. LAVE: It's my understanding that, because I was on the commission, the IOM, the nursing home quality commission was that actually HCFA had proposed deemed status for nursing homes and that it was the advocacy groups that were extraordinarily concerned in fact that it not have deemed status and that it be subject to state regulation. So HCFA did propose, but this was during the Reagan administration and the advocacy groups, I believe it was they who forced the IOM committee which then set the stage for the next set of regulations.

DR. ROWE: As someone who seems to at least one day a week have the opportunity to welcome some inspectors or regulators to our institution for some period, and I have had a fair amount of experience over time with a variety of approaches. And I think I speak for my colleagues as well

that the changes in the approach and the content and the style of the Joint Commission, their interaction with us over the last several years have been remarkable; exceptionally positive.

By that I don't mean to imply that they're any easier on us at all. I think we're working harder now than we were before but we're getting a lot more out of it. I've had the unusual occurrence of having a sentinel event occur in the middle of a Joint Commission survey, and it's just like all the alarms go off at once. Even the head of the survey when this was brought to his attention said, oh, my goodness. But they are able to work with us and I think it's very impressive and very helpful.

My question, Margaret. You didn't mention, when you were talking about matters arising, if you will, you didn't mention your efforts to accredit networks or systems. I think that with respect to the Medicare program and to the evolution in health care that's probably an increasing area of interest to HCFA and certainly to providers. Would you like to say a few words about that?

MS. VanAMRINGE: Sure. Thank you. I did not

focus on them because my thought was that you were more interested on the fee-for-service side. But we are very pleased with our network accreditation program because it is very unique from two perspectives. First, our accreditation standards in managed care can encompass any type of managed care delivery. So we can do PPOs, integrated delivery systems, and HMOs.

We have found, secondly, that these standards have done a great deal to help bring the integration of services together. When we look at a network we're finding that one of the challenges that is out there is to make sure that services can be coordinated, can interdigitate, and that the hand-offs that occur in health care can be done in a way that actually maximizes patient outcomes.

So we're very proud of those standards and we think that this will go a long way, I think, in bringing quality of care outcomes to a greater place in the managed care arena. Our accreditation program on this side is growing. We are growing very rapidly, and we're finding that there's greater interest now in provider health care systems being accredited as a network more and more.

MR. MacBAIN: I think in listening to your remarks combined I heard you describing two different processes, one which I think of as quality assurance which is really a regulatory binary process that determines whether a given institution is either above or below some minimum standard. That it reflects a regulatory concern with achieving some minimum level of space. And a quality improvement process that is the direction that accreditation is moving in that is more collegial, focused on process and improvement; a more continuous relationship.

I think particularly in Kathleen's remarks I heard some skepticism about whether both of those can be achieved within the same agency. I wonder if you'd care to elaborate more on that.

MS. SMAIL: I think the point that I was making was not that quality improvement and quality assurance as in regulation would necessarily be in the same organization. I think that the organizations that are out there need to work together. I think there are very different roles, but I think they dovetail very well. There is, of course, some

blurring of lines.

For example, we don't have in Oregon a requirement that -- and I don't think there's a federal requirement -- that says that providers have to report sentinel events to us. But in some cases we've had that happen, and in particular one hospital we did require that after a major problem occurred twice. We have found that that's helpful for the provider because then they report to us not just what happened but what steps they've taken to prevent it from happening again.

But primarily, the outcomes don't fall in our purview. For one thing, state survey agencies don't have the ability to hire individuals who are in current clinical practice to review things. So we don't have that expertise. We rely on the PROs, for example, the networks, and the Joint Commission for that.

MS. VanAMRINGE: I think you're right, it is very hard to have both of those qualities in a single organization. Although I would say from the accreditation standpoint, we should be able to recognize when there isn't basic quality assurance going on.

I think that it is the strength of the partnership that allows for both quality improvement and quality assurance to occur. It's not that either of our organizations should be all things to all people. I believe that we've had such a strong partnership with the state survey agencies and HCFA that we've been able to accomplish both and each play to our own strengths very, very well.

DR. KEMPER: I guess just to follow up on that, I guess I wanted to ask Rachel. You had talked about, if I understood it right, trying to make the survey and certification activities most distinct from the quality improvement activities. I wanted to understand what was behind that because it seems to me the whole structure side of the health care delivery is just one piece of a quality improvement effort and the quality monitoring information could help target efforts to look at whether the stop sign is there or not, and whether the basic quality is being provided.

So I just wanted to understand why you were moving to separate those, make them more distinct, rather than to integrate them as part of an overall quality improvement.

MS. BLOCK: I think it wasn't so much to imply that we were attempting to segregate the activities so much as that we felt it was important, and I think that the IG report on hospitals particularly highlighted this in fact as one of the most prominent issues. That the first step is be clear about which hat you're wearing, which function you are attempting to conduct. If it is under the rubric of quality improvement in the penalty-free environment, or is this a regulatory quality assurance focused activity? It touches on a part of what Joe's question was earlier and it is implicit in a couple of the other questions that we've had.

I think that we view quality improvement as an extremely important part of the overall fabric, that in defining the new PRO scope of work that Margaret touched on and I'm sure Jeff will talk about at much greater length, we really tried to make the vision of the peer review program more explicit in terms of the quality improvement function.

But that there is still a regulatory component to the overall system and that we need to be clear when we are in fact utilizing or discharging our regulatory responsibilities, and that in fact while we would hope that

quality improvement would be successful in addressing many of the problems in terms of care delivery, it may not be the answer for all problems. And that the law does prescribe or provide the ability to impose other kinds of penalties to address conduct or activities by providers that really fall below, explicitly below, the standard that we should expect.

So I agree with the comments of my co-panelists in terms of these need to be complementary activities, but my comment was intended to highlight the fact that in order to be complementary you also need to be clear about which is which.

DR. KEMPER: I guess my second question has to do with the frequency of surveys, and you mentioned that in some cases it was once every 10 years. I know on the nursing home side you make some effort to target visits on facilities where there's more likely to be a problem in. To what extent do you do that across the board and actually target the use of those survey resources?

MS. BLOCK: By law, nursing homes have to be surveyed annually, and the budget essentially drives the frequency of the surveys in other provider types. Over

time, as you look through the list, you would see that with home health we've gone anywhere from a one to a three-year cycle. For non-accredited hospitals we survey more than we do the accredited hospitals because that is viewed as more of an oversight activity. So part of it is based on the accrediting context, which is an important part of the total fabric, part of it is budget driven, part of it is based on the sensitivity, if you will, of the kinds of health care issues or the risk of the population that's being served in a particular provider type.

One of the areas where I think we hope to target additional resources in our upcoming budget is to the dialysis facilities where we have had problems meeting what we think is a reasonable survey cycle. But again, these are national or aggregate averages that we seek and at the state this could vary widely. I think it is also important to note that while these are the funds that the Medicare program provides for its purposes, that states in fact commit significant state resources that complement those activities as well. So it's part of the overall system even though it isn't coming directly through the Medicare door.

MS. RAPHAEL: I just wanted to follow up. What percent of HCFA's budget goes to the kind of quality assurance activities that you describe? Is there any way to give us some gauge of that?

MS. BLOCK: I couldn't tell you percent-wise. I would really have to go back, because I'd want to try to capture the full scope between the PRO budget, our budget for survey and cert and so forth. I just don't know the other budgets well enough. I do know that our target for FY 2000 just for survey and cert related activity -- this would not include HCFA's administrative expense associated with the direct activities that we perform, but rather the dollars that actually go to states for the purposes that we've been talking about is a little over $200 million.

DR. WILENSKY: Rachel, maybe you could -- and Kathleen, I'll let you respond in a minute to the previous comment. Maybe you could ask someone to put that information together so we could circulate it to the commissioners. If that's an issue, tell me who we should ask. If that's a problem for you to do the request, tell me and we'll make the request otherwise.

MS. BLOCK: I can certainly pass the request along and make sure that it's met.

DR. WILENSKY: Thank you.

MR. SHEA: And if we could get the information over time I think it would be helpful. How does it compare to eight or 10 years ago.

DR. ROWE: And expressing it as a fraction of the amount spent on fraud and abuse.

MS. RAPHAEL: And do that over time.

[Laughter.]

MR. SHEA: But it's also worth noting in that same respect how much money has been saved through this aggressive fraud and abuse program.

DR. WILENSKY: Kathleen, you wanted to comment to Peter's question?

MS. SMAIL: Yes, I wanted to follow up on Rachel's comments in response to Dr. Kemper. State survey agencies, in planning which surveys they're going to do if they're not doing long term care, for example, or home health, which have prescribed frequencies, take into account a number of things. First of all, complaint histories on the part of

the provider. Secondly, the length of time it's been since a previous survey. A lot of this is cerebral, you know, judgmental, but whether there have been a number of administrative changes or change of ownership. Those factors are all taken into consideration by the state survey agencies.

I should point out one difference in Oregon is that, I believe that -- I could be wrong on this but I believe there is a federal regulation that precludes accrediting organizations from having to share their survey findings with state agencies, and some states may have their own state level. In Oregon, for example, for state licensure purposes we can use deemed status for hospitals, but in order for hospitals to achieve deemed status for licensure purposes they must send us their most recent accreditation report. So we have that on file and that's publicly disclosable.

DR. KEMPER: Do you think there's opportunity for improving that targeting? The IRS is pretty good at deciding who to audit based on --

MS. SMAIL: I think HCFA's increased use of data

systems, such as the OASIS which is for home health, is going to focus on that and I think that will be helpful.

DR. WAKEFIELD: A comment and then a question, and the question for any or all three of you. The comment I'd like to make actually follows up on the point that Woody was making earlier, and I would have raised the same line of concern around issues of staffing, in part because there's a very large risk management company that I do a little bit of work with that in its ongoing study of professional liability lawsuits, recently that ongoing study has revealed for this large company issues relating to nursing practice specifically and nursing practice patterns contributing to adverse patient outcomes. They tied those in their review of their own data from their hospitals, they tied that to primarily issues around the failure of nurses to adequately monitor and assess changing patient status.

So I think this is a real concern and probably speaks at least in part, one would guess, to some of the reorganization, reengineering, changes in staffing that might be occurring in some of those facilities. But the jury is still out in terms of what might be driving this.

What's clear is there's some liability claims related to this area of practice that they hadn't seen historically. So that's just a follow-up comment.

My question, from your three different vantage points -- and now speaking to rural issues -- do you hear different kinds of concerns expressed by rural facilities, rural providers that are being surveyed, certified, accredited, different concerns expressed from rural versus urban facilities related to, for example, cost burden for participating in accreditation and survey? That is the cost burden of data collection and use of resources.

Do you heard different kinds of concerns expressed by rural facilities that might relate to the need for, for example, a common set of rural standards that are relevant to rural providers across the board, standards that might be sensitive to maybe more of a rural context rather than an urban context? Are you queried much by rural providers along those lines?

For example, Kathleen, you made one comment about, I think it was the expectation that your 12-bed hospital is expected to meet some same standards that that level one

trauma center was expected to meet. I'm not pitching this question to suggest that there should be some second tier set of standards that are not as good as what's being applied to urban facilities, for example. I'm just saying, are some of the rural facilities coming to you and saying, we have a different context? Frontier health care looks a little bit different than Johns Hopkins health care, and maybe what they're being accredited on or surveyed on are questions that they might feel are not quite as relevant to the types of practice they engage in.

So overarching question, do you hear different concerns express to you from rural versus urban facilities?

DR. WILENSKY: I'm going to ask you to have very brief answers. We have two more people to question and I want to get on to our next session.

DR. WAKEFIELD: It was a long lead-in; is that what you're saying, Gail?

DR. WILENSKY: It was a long lead-in.

MS. SMAIL: So my answer should just be yes?

[Laughter.]

DR. WAKEFIELD: No, I'd appreciate a little bit

more than that.

MS. SMAIL: We do have different concerns presented to us. On the one hand, most of the -- in Oregon, the non-accredited hospitals are rural, and the urban hospitals are accredited. I don't know of one in an urban location that isn't accredited. I think that rural hospitals face challenges in terms of staffing, not only nursing staffing but physician staffing. That small town that has the 12-bed hospital with the 39-or-whatever-bed long term care facility attached that probably supports it, has had challenges at finding more than one physician. So it's problematic.

I think they also have some problems in terms of reimbursement. I am very weak on reimbursement because I don't know that much about it, but it seems to me that teaching hospitals might get a better reimbursement rate, for example, than a rural hospital. At the same time, they have a great deal of community support and in many cases are district hospitals. So there are different concerns.

I think HCFA has -- there's a new program, the critical access care hospital. In Oregon, it's just getting

off the ground. We've revised our licensing rules, so we're working on that.

DR. WILENSKY: Margaret?

MS. VanAMRINGE: The answer is yes, again. We have a small rural task force which looks at these issues. Our task force on small and rural hospitals speaks to these issues very frequently, and I think I'd like to mention two specific areas. One is, we also believe that there should not be two levels of standards of care. So we have one set of performance measures, but we have survey protocols that differ for rural hospitals. That allows the flexibility to meet the standards through different mechanisms.

Also, I would say that while all hospitals are concerned with cost, the biggest issue there is whether or not the investment that's made on data collection activities will actually have a pay-off. Because if you are collecting on measures that you only have one, two, maybe three patients in that particular area, that doesn't seem worth the money. So the issue is how to come up with the matrix for the small hospitals where the investment will really pay off, and that's what we're looking at now.

DR. LAVE: I have two questions, one of which is this relationship between deemed status and accreditation. I sensed a slight difference between Kathleen and Margaret on this issue. I guess the other thing is whether or not we could talk about that a little more.

The other thing is that I'm puzzled about what it means to be deemed status. I know it means that I meet the qualifications. But then I thought it also meant that I didn't get surveyed so much. So I thought that there was -- and then you told me that you did survey them.

So that's when I got a little confused about, if I am deemed, what functions HCFA doesn't do, and whether or not this is something, deemed and accreditation is something that we should think about at all. Particularly I noted the tension around things like home health agencies and the ESRD and the kidney dialysis facilities. So I'd like just to have a little more thought on the deemed status issue.

The second question is somewhat different and that is whether or not this issue of other penalties is something that ought to be discussed or whether or not it's a reasonable thing to consider. I know that during the

nursing home debate that there was a lot of concern that you could either kill somebody -- to penalize -- that the instruments that you had at your disposal were so harsh that you weren't likely --

DR. WILENSKY: It was the atom bomb strategy.

DR. LAVE: It was the atom bomb strategy. And what you're telling me is that that really is what is left is the atom bomb strategy. And whether or not in fact these other kinds of incentives, shall we say, to encourage people to come into line to make sense to think about in today's environment of continuous quality improvement.

MS. VanAMRINGE: I'm not sure what Kathleen meant because I had that same question actually about the difference between expanding deemed status and support of accreditation, so maybe I'll let Kathleen talk about that. I do believe that there needs to be a variety of penalties in the system because people respond to different things, and different issues are more amenable to remedying with different incentives.

Obviously, the meat ax approach is very fruitful if a provider does not want to do what's necessary to change

at all, and that's where you cut them out of the system. But other organizations need time to grow, and if they're moving in the right direction, then there should be incentives for them to do that; penalties perhaps less severe if they don't make their progress points as expected.

But allowing them to stay in the program allows someone to monitor them. When you take people totally out of the program, then no one is looking at them at all.

DR. LAVE: I think the concern also is that because the penalties are so harsh you're not going to impose them. So I mean, there is that.

MS. VanAMRINGE: That's right.

DR. WILENSKY: Rachel or Kathleen, did you want to comment?

MS. BLOCK: Just on the penalty issue. I certainly didn't mean to imply that the regulatory system meant that the only option was an atom bomb strategy. In fact, for nursing homes in particular there is a fairly broad array of options in terms of the types of penalties that are available. You probably know that the survey results and deficiencies are arrayed according to a grid

which attempts to capture the severity and the scope of the problems so that the penalties are in fact geared to those issues.

In addition, within the broad tools that are available, there is latitude in terms of the actual amounts in the case of fines, or the duration in terms of number of days or number of patients to whom the penalties can apply. Ultimately, there is the option to terminate the provider. It is used very infrequently.

So I wanted to emphasize that we view the penalty system for nursing homes in particular as operating really a broad array --

DR. LAVE: No, the question is whether that should be applied to the other providers. That was the question, whether or not in fact that the limited set of options for providers other than nursing homes...

DR. WILENSKY: If you would like to get back to us on it that -- there may also be a legislative issue with regard to that.

I had a question I wanted to ask. I think it's primarily directed toward Kathleen and Rachel, and then I'd

like to go to our next session.

I have heard from people who are providing services, because they tend to come bend my ear as MedPAC chair that, particularly in the nursing home area but not exclusively in the nursing home area, a frustration on the part of the multiple levels of certification and survey. When Jack said he has the pleasure of about once a week welcoming somebody in who's doing an inspection or survey of some sort --

It has seemed to me that this imposes not only burdens on the providers, but therefore, the use of resources in ways that are not directly related to patient care, and perhaps not the best use of services. I didn't know whether there was any thought being given to try to have more in the way of consolidated reviews go on.

Again, the sense I had was perhaps because of differences in state regulatory structures versus what HCFA was requiring, or because of the distant relationship between what HCFA does and the contracts it has with the health survey and cert groups at the state level who then have some discretion at least as long as they meet HCFA's

direct requirements, that you get cascading levels of inspection and regulatory structures which seem to take an added cost, at least as it's been explained to me.

I don't know whether this is an issue that has troubled HCFA or the states or the surveyors, but it strikes me as one that, to the extent there is legitimacy to this issue, is in a time when we're trying to reduce spending because of reduced Medicare reimbursements, may well be diverting resources in ways that aren't particularly helpful to improving patient outcomes. I wondered whether you'd comment on that.

MS. SMAIL: I just want to state briefly that the states recognize that and we've made a suggestion, for example, for conserving of resources and to improve the validity of the validation surveys that one option might be to have that state agency survey occur simultaneously with the Joint Commission survey, for example, in a hospital. I should point out that validation surveys have occurred traditionally at about 5 percent. So in Oregon, for example, that means two surveys a year. So that's not a huge number; very small.

Secondly, we do --

DR. WILENSKY: Is that for the hospitals only or is that also for nursing homes?

MS. SMAIL: Nursing homes, I don't believe have been given deemed status, and this is for providers which have deemed status. There's a difference between -- hospitals that are accredited all have deemed status. Home health agencies and others that are accredited have to request deemed status. So there may be some that are accredited that are also getting surveys.

But we've made a strong effort in Oregon, and I'm sure other states have, to coordinate survey efforts, inspection efforts, and in some cases, aside from coordinating, to accept others inspection reports without duplicating them. A low level example would be, when we do a hospital survey we look to see when the county sanitarian was there to inspect the kitchen and if it was within a certain recent period we accept that report rather than duplicating it.

MS. BLOCK: We really commit fairly limited resources actually to the oversight surveys, look-behind

surveys, the validation surveys. To the extent that they occur on the nursing home side, what we're doing is we're evaluating the states performance of the survey. In those instances where we're talking about accredited providers, we generally are validating the survey results as well as assessing the performance of the accrediting body in conducting the survey.

But particularly with nursing homes, we're primarily focusing on validating the states performance of the survey as opposed to the provider. And the actual presence of federal surveyors in general a pretty minimal one. So I would like to know a little bit more if there were specific examples of where those additional layers were occurring, because at least in terms of the data that I know about what federal surveyors do, that is not a concern that I have heard. If anything, I think we've heard more the opposite, that we aren't out enough.

DR. ROWE: Have you heard from hospitals that you're not surveying enough? I just want to make sure.

MS. BLOCK: I wasn't referring to a particular provider sector so much as the overall observation that we

need to devote more resources to those kinds of activities.

MR. SHEA: Gail, I wanted to follow up on your question by just making the comment that I think this is a big issue just as it is an issue in a lot of the things that we talk about in terms of recommendations that we might make. But as example of what I think is just an imbalance that is at the heart of this whole situation, from the consumer side there are lots of people who argue, we're not getting nearly enough assurance that what's going on in these facilities is even meeting minimum standards.

So on the one hand you have the providers saying, we're just spending lots of resources on it. And on the other hand, the consumer is saying, we're not getting out of this what we think we need at a minimum. So just a comment on that.

And a second one is that, in addition to the burden I think there's another one which is information disclosure. Particularly as you get electronic transmission as the Joint Commission is getting into, providers are very concerned about putting information out there in terms of their own financial or business viability. Yet there's just

going to be growing -- there is growing demand now and it's going to grow even faster as some information becomes available, to make available much, much more of this.

This has been a debate for a while, but just look at the Internet activity that's going on now and think about what's going to happen when the access to the Internet services not only gets broader but gets more sophisticated from the consumer point of view. The idea that the Joint Commission has all this data that's being sent quarterly on performance measures, there's going to be enormous pressure to say, fine, we want to see that data too, and not unidentified data.

DR. WILENSKY: I want to be clear. I was not suggesting a lack of effort in terms of doing quality assurance and quality improvement. But what I was responding to, what had been raised to me was overlapping, duplicative, and sometimes contradictory requirements that occurred for a given institution, which I don't think is particularly helpful either for the patient or for the more efficient use of resources.

MR. SHEA: I think there would probably be broad

agreement on that, but I was just saying that there's another tension here that was surfacing.

DR. ROWE: Can I respond to Gerry?

DR. WILENSKY: Yes.

DR. ROWE: Gerry, I agree with what you're saying in general except with your assessment of the appetite for this information. We have been surprised -- in New York there's a lot of publication about mortality rates and morbidity rates for cardiovascular procedures in the newspapers every year, and we have been surprised at the relative lack of interest and the lack of an impact of those data on referral patterns, patient interest in coming to various physicians. It's almost had no -- it has impacted behavior of hospitals to improve because they want to rank better.

One of my faculty, Bruce Vladeck, told me that when he was at HCFA --

MR. SHEA: Just picking a faculty member at random.

[Laughter.]

DR. ROWE: Right. He told me that when he was at

HCFA and he decided not to publish the hospital mortality rate national data that he received about 500 letters about that, adverse comments about that, three of which were from non-media representatives, and the rest were all from the media. It seems as if, at least so far and it may with the Internet it's going to change, and I think it would be good. But so far the appetite amongst individuals and their capacity to change their care behavior based on this information has been surprisingly light.

MR. SHEA: Although some of us think that's not a lack of appetite as much as it is the usefulness of the information. I think consumers have judged this to be not that relevant to them, or not anything that they can actually use to change their care patterns.

DR. ROWE: I mean, the place with the worst mortality rate in New York City for cardiac surgery still has the biggest program and lots of patients. You would think year after year they'd look at it and they'd say, I don't want to go there any more. But it doesn't seem to have an impact.

DR. WILENSKY: Although it's not clear that having

the media being the ones that were responding to this loss of data didn't mean that people who rely on the media with regard to translation didn't in fact --

DR. ROWE: Absolutely.

DR. WILENSKY: They were registering their loss or lack of information in a different way.

DR. ROWE: That's right.

DR. WILENSKY: I think I would prefer to go on. Maybe we could get to a --

MS. BLOCK: Could I just make two very quick follow-up comments though? On your issue regarding duplication of effort. Margaret mentioned the workplan that we're actually working with the JCAHO on about how to strengthen and clarify our respective roles. I think that will go a long way to providing a framework within which we could address those issues more effectively.

On this issue, again I just want to mention that the Internet use of access to the nursing home survey results has been extraordinary. I don't know what people are doing with it. But it has been extraordinary, and to the extent that you can differentiate whether these are

commercial users or real people, there is a very high percentage of real people who are accessing this information. And we continue to anticipate significant enhancements to that system as a mechanism to provide public information.

My point there is simply being that I think you need to look at it, as we would suggest looking at quality, that there are an array of tools and approaches that could be used to think about how to inform and help the public be better purchasers of care. And we view it as a very important feature in our overall approach to quality, particularly on the nursing home side.

DR. WILENSKY: Thank you very much.

MR. SHEA: If there were more time, I would like to pursue this discussion about the coordination between HCFA and the Joint Commission because that's really one of the big, if not the biggest thing, that comes out of the inspector general's report is what's the relationship, and particularly how does HCFA benefit. So if there's anything that the two organizations want to collaborate on sharing with us as follow-up in terms of where this is going and a

workplan, it might be useful to see.

DR. WILENSKY: I am sorry to cut off this discussion. We had thought an hour and-a-half ought to have been more than adequate. It's something where we need to have a better distribution of our time between presentation and questions and answers that we make sure we can get this kind of exchange. Thank you.

Jeff, David, Bill Golden? If each of you can try to keep your presentations to no more than 10 minutes we'll make sure that we have enough time for discussion.

MS. FINGOLD: We have a second panel this morning following up on improving and safeguarding quality. This panel is going to talk about the peer review organizations sixth scope of work. With us this morning we have Jeff Kang who is director of the Office of Clinical Standards and Quality at HCFA. We have David Schulke who's the executive vice president of the American Health Quality Association which is the national association of peer review organizations. We have Dr. William Golden, who is with the Arkansas Foundation for Medical Care and is the president of the American Health Quality Association.

DR. KANG: Thank you very much. Actually, I'm going to try to be quick and catch you up. There's a hand-out that just went around and this is going to be a very short synopsis and the highlights of that. I should say, Dr. Wilensky, just as an aside, this morning I spent some time with the Robert Wood Johnson Foundation fellows and the third question I got was, what do you think about MedPAC? And I said, interestingly enough, I have great respect for the work they do and I'm going to testify later.

[Laughter.]

DR. NEWHOUSE: We give the same answer when asked about HCFA.

[Laughter.]

DR. KANG: Touche. This is all in your package, but I'm just going to go to -- I need to follow-up on the first panel here. This is part of an integrated HCFA quality strategy. It is primarily based around performance measurement and it assumes here that we can measure quality, either plan or provider specific. With that assumption, on this bottom row here there are roughly five interventions that we can consider. The first really is what the first

panel was talking about, the notion of the regulatory approach; should there be minimum performance standards and performance in enforcing that?

The second, which we will spend talking about on this panel is the quality improvement approach. Based on performance measurement, can you get plans or providers to actually improve their quality over time. So one is setting the minimum requirements, the other is a continual quality improvement approach.

We actually in this regard believe that the enforcement side or regulatory side is our "penalty-full" or "penalty-replete" approach. That's what you've just been spending a fair amount of time talking about. The PROs, or the quality improvement approach really is our penalty-free environment, and in fact it is confidential and under the peer review statute is -- the provider information is actually protected from disclosure.

The third, which you just spent some time talking about is the notion that if you can measure plan or provider performance there presumably is also a desire or need to publish that data for consumer information and choice.

The last is, presumably at some point, to the extent that we get data, we should be looking at payments, at our payment structure to encourage quality.

Then the last which has had some interest is this issue of, assuming we can measure quality, should we be paying more for quality? HCFA doesn't have that statutory authority currently but there is some interest in this notion. That all assumes that we can actually measure quality.

That's the broad context here. I'm going to focus on this box here which is the PRO program and the penalty-free quality improvement approach.

What are PROs? They're federal contractors. There's one in each state, established by Congress, generally physician led. I think the most important bullet here is this fourth bullet, that in the last eight years we have shifted the PRO program from this inspect and punish model, the regulatory approach, to an educational kind of model for quality improvement in this penalty-free environment.

I'm going to talk about the scope of work which

began last month for the next three years and I'm going to focus primarily on this task one and task three. This just started occurring and it's in all 50 states; it's national.

The major themes of the new contract, we in the fifth scope of work had a lot of local quality improvement projects. But what we really decided to do here was nationalize the program and actually align a lot of the performance measures with our GPRA measures that Congress also asked us to do.

So to take an example, one of our GPRA measures is the improvement of mammography rates for beneficiaries. As we know, there is under-utilization in this area. One of the PROs sixth national quality improvement projects, so all PROs will be, in all states, working on improving national mammography rates. We will actually be measuring those and creating a surveillance system based on each state, and actually rewarding and assessing PROs' performance on the improvement over a three-year period in baseline mammography rates within their states to three years later.

That is in our GPRA performance measure and we would be tracking that nationally and, obviously, be

reporting back to Congress whether we improved.

Now one of the things we've been very sensitive to in this issue of PROs working in the Medicare context is the notion that there are other interested purchasers, plans, providers, consumers which we ought to engage in a collaborative fashion in order to reduce burden. Even though this is for the Medicare program and that by statute is what the PROs are limited to, we believe that if, to the extent that there are other purchasers or like-minded public health officials in the states that are interested -- let's take the mammography example -- in working to improve mammography rates, that the Medicare program will actually benefit greater by collaborative and community partnerships than just Medicare acting by itself. This is the notion that the rising tide lifts all boats.

So really are aiming the PRO program more to create what we're calling community partnerships largely for the purposes of reducing redundancy and maximizing the actual clinical quality improvement effect. Consistency reduces burden, unified messages increases the impact, so that's where we're trying to move the PRO program.

Now how did we get into these six national quality improvement areas? In essence, there were four criteria to get into this. It was high impact on Medicare beneficiaries, so there are the high prevalence conditions; the usual suspects, heart failure, stroke, pneumonia, et cetera. That there are actual clinical process measures that are strongly linked to desired incomes -- outcomes, I'm sorry.

[Laughter.]

DR. ROWE: It's the outcome measures that are related to the income, unfortunately, as we all know.

DR. KANG: The linkage is -- obviously we're looking in the literature that there's a science base for this. Also there needed to be room for improvement, and then that the PROs have actually have experience in the fifth scope of work of creating systematic interventions that actually have demonstrated improvement.

This is an example of just current Medicare rates nationally in some of these process measures and how there is dramatic room, there is plenty of room for improvement here. These are the six national quality priorities. In

your hand-out are much greater detail here, but again they're the usual suspects. These are the big prevalent conditions for Medicare.

The one thing here that I would like to emphasize is most of these things are in the inpatient setting. We are slowly, and very interested strategically in beginning to move toward the outpatient setting in this area with regard to clinical care. I think most of the action, quite frankly, here will be with diabetes.

Now the last thing I just want to mention is Medicare+Choice. We actually with regard to -- most of that was in the fee-for-service context. In the Medicare+Choice context we actually have in our new QISMC requirements for Medicare+Choice plans a requirement for them to do quality improvement projects. In year 1999, the first is diabetes. What we are trying to do here is we have a mandatory requirement for Medicare+Choice plans to have a diabetes quality improvement project.

We are now offering the PROs as a vehicle for technical assistance on those quality improvement projects. It's not mandatory that plans work with the PROs, but the

assumption is if you're in a market with five plans working on diabetes quality improvement that they would also come to the conclusion that if all of them work in concert via the PROs as a convening mechanism, that we would end up with much more quality improvement than each of the five plans working by themselves. We would also work with the fee-for-service system.

The notion here is to reduce the redundancy of effort. Providers here will tell you that in a managed care market if there are five plans each of them quality improvement, they're each doing -- interested in the same issues, doing it a little bit different, and there's a tremendous amount of redundancy and chaos. We hope to try to actually reduce that. We are engaging other like-minded purchasers, we've asked the PROs to engage other like-minded purchasers in their communities to actually come on board, to the extent that they are interested in diabetes or heart failure or whatever it is.

Let me stop there. I'm sorry that I ran beyond my 10 minutes but I think that's enough to whet everyone's appetite.

DR. WILENSKY: David?

MR. SCHULKE: Good morning. Dr. Wilensky, Dr. Newhouse, members of the Commission, it's very good to be here. My name is David Schulke. I'm the executive vice president of the American Health Quality Association, which is the national representative of the nation's network of quality improvement organizations.

I'm calling them that and I'll draw attention to that because the PROs of the '80s are not the quality improvement organizations of the '90s, just to reinforce Jeff's point. These organizations now are increasingly sophisticated. They have a lot of different customers and they're providing a lot of different services to those customers. They're working for state Medicaid programs. They're working for employers, commercial managed care plans, and for state insurance departments doing external review or appeals of health plan decisions and denials and so forth.

My job today is to try and provide a quick overview of the QIOs in relation to their Medicare work and how that advantages some of the agendas that I understand

the commissioners have. And also, provide a good handoff to Dr. Golden, who is the president of our association, and will talk in more detail about the Medicare PRO function.

I think it has to be said, without question though, that the single largest and most important customer of these organizations is the U.S. Health Care Financing Administration. So the Medicare program is still the main focus of these organizations, and in some states almost the exclusive focus of these organizations.

With respect to Medicare quality improvement work I'll be very brief. I want to make two points here because you've already heard some and you'll hear more. The PROs will be accountable for showing movement in the desired direction on a set of 22 clinical indicators through the collaborations that they have in the community with providers and practitioners and plans and others. They will be held accountable even though none of these folks are required to work with the PROs in their Medicare context on quality improvement projects.

The PROs do have the same authority they always had to investigate complaints and to look into dumping

problems and other case review activities. But when it comes to quality improvement, that's a voluntary collaboration, and if people want to stiff the PROs or ignore them, they can do that.

Fortunately, the PROs have been successful in getting approximately three-quarters of the hospitals, because of their inpatient focus, in each state to work with them on these projects voluntarily. But it makes their accomplishments all the more remarkable because this has been not only a penalty-free environment, but one where people have been willing to come to the table and do a lot of work for which the PROs are held accountable.

I'm going to talk briefly about the payment error prevention program because no talk about the PROs and the sixth scope of work is complete without address the payment error prevention program, and I admire Jeff very much for being able to avoid doing that.

[Laughter.]

DR. KANG: Dr. Wilensky said I only had 10 minutes.

MR. SCHULKE: I'm going to give this a very quick

overview.

The new Medicare contract, as probably most of you know, requires the PROs to work with hospitals to reduce payment error rates. So much attention has been given to this that you might think that there's a lot of new aspects to this program and that there's a lot of new authorities and that the PROs are doing a lot of new things. That's mostly not true. The one thing that is new about this approach is the educational focus. That is that they're supposed to work with the hospitals to figure out ways to reduce payment errors prospectively in the future.

The things that are not new are the things that make people nervous and have always made people nervous. For example, recoupment. If a hospital has been paid erroneously some money, the PROs have always, under the federal law and under their regulations and under their manual instructions, been responsible for an elaborate case review process which would make a determination as to whether or not there was an inappropriate payment, and then would pursue recoupment. This activity has been going on all along, and has been going on since 1984 when the PRO

program got implemented in October of that year.

It's very unlikely that the clinical indicators, the gathering of clinical data used in quality improvement projects will have much interface at all with the PEP program. The kinds of data that are gathered for the two activities are very different. The personnel involved are typically very different, both at the hospital and at the PRO end of that relationship.

Probably the biggest danger associated with the PEP is that perceptions will overtake realities. That is, that people will believe or come to believe that the PROs or working with the PROs on quality improvement will somehow expose them to greater risk than they were exposed to in the past. That would be very bad, and if it happened that would constitute a risk, a poisoning of the well, a violating of the penalty-free zone and that could cause problems. We're trying to explain to everyone out there exactly what I've told you so far, that you've been dealing with these folks on these activities for many years and the PROs are very accountable for being fair and even-handed in doing this.

The other thing that we're pointing out to folks

and I would put on the table for you to consider as well is that claims data are inherently flawed in terms of making judgments about what's an error and what's fraud. The people who would be working on these issues, if it weren't the PROs, would not be physicians, and all of the due process and the elaborate accountability procedures that are built into the PRO program would not be in place.

I think that it's a lot safer for everybody to have physician-led organizations responsible for reviewing these cases and making these determinations. I don't know who else would do it if the PROs didn't do it, and the PROs are enthusiastic about doing it well and doing it wisely and taking their responsibilities seriously.

Let me say something about survey and certification, because I was asked to address that. We have a couple of ideas on this, but I want to start by saying that, obviously you could tell from your last panel that you could talk about survey and certification for more than a day, let alone for the morning hours.

I think that it's very important to understand or consider that long term care survey and certification is

very, very different in many, many ways for other survey and certification activities. It's different because of the presence of a very well-organized and well-informed consumer presence. I think that a discussion by the Commission would be more complete if the consumers were represented in the discussion at a table such as this one and would hope that you would consider that for follow-up at some point.

They have substantive, not merely political impact on the deliberations of the government, the Congress and the administration, over many administrations. The people responsible for this have been recognized and given prestigious awards for their impact on the health quality system just as recently as last week when the Lienhart award was given to the founder of the National Citizens Coalition for Nursing Home Reform. That's not given lightly to people who are rabble or rabble rousers, but that is a recognition that there is a serious contribution here and I would ask that you folks take that into consideration as you're looking into this issue further.

I was asked to distinguish a little bit between quality assurance and quality improvement activities.

Traditionally, people hold these things very far apart. They're supposed to be very different. The penalty-free zone, the penalty-replete zone, many other metaphors have been used to describe the difference. I think there's a couple of important distinctions that can be made that are functional in nature.

One is that the enforcement of minimum standards is prohibitively expensive and seldom effective against all but the most clear-cut violators. It's very hard to take away a property right or impose penalties on people, and it should be very hard to do that. In our country we believe that that's something the government doesn't do lightly. So there are lots of due process safeguards, and you can't go after somebody and take away their money, or fine them, or take away their license to operate without a lot of procedural safeguards being addressed.

It's likely, therefore, that you cannot get to many of the quality problems in the system because most people's quality problems, most of the quality problems that are documented in the literature are not the result of clear-cut violations that are prosecutable, and fineable,

and punishable. Most of them are another set of problems, system problems that have been discussed here and published in your reports in the past.

A second important distinction is that quality improvement efforts can far exceed in what they accomplish the quality results of a minimum standards-based approach. Sometimes these things can work very well complementarily. I think we've seen in the past -- recently, the Joint Commission published some standards on pain management for hospitals. This caused many hospitals to go to the quality improvement organizations to figure out ways to improve their pain management.

We've also seen with the New York State CABG experience that when there was some pressure on hospitals from one source that did spur a lot of quality improvement activity which actually improved quality much more than you could ever have accomplished if you'd simply eliminated those hospitals with some sweep of a wand or a ceasing of all referrals. Even the best facilities improved their mortality rates because of all the quality improvement work that went on.

I'll make one suggestion. Long term care facilities in particular have egregiously low immunization rates. This is a national goal of the U.S. Department of Health and Human Services to improve immunization rates. It's a national goal for the PROs under the sixth scope of work. It's likely that a survey and certification approach to this by itself will not succeed and that systems are needed to try and ensure that people get lifesaving vaccines.

It's possible that an announcement could be made, a stated intention could be enunciated by the government, by the states and by the feds that they're going to be looking at this as an enforcement issue in the near future and that nursing facilities ought to start working with the PROs to improve their immunization rates before someone comes in and starts wielding fines and threatening certification status of facilities.

The last area that I would briefly comment on is that the PROs, by virtue of using these well-vetted, scientifically valid indicators to improve quality and work with providers and others, are in a good position to reach

out to employers and other purchasers in the marketplace than Medicare to seek agreement, promote agreement on those measures, and to promote use of those measures in quality improvement and in other activities.

Whether eventually employers and others use that for report cards, or whether they use it for quality improvement is a decision that is a fork in the road that is down the ways a bit. But we think the PROs can be an important vehicle for promoting agreement and reducing some of the chaos on indicators and would urge you to look at them that way.

Thanks for your attention.

DR. WILENSKY: Thank you. Please try to keep your comments to 10 minutes. I really don't like having to cut off the commissioners from asking you questions or making comments.

DR. GOLDEN: Sure. I plan to. Thank you very much. Good morning, Madam Chairman.

Just to give you a little bit of background on myself, I am the director of the division of general internal medicine at the University of Arkansas' Medical

Sciences and since 1992 I've been the principal clinical coordinator at the Arkansas Foundation for Medical Care, the PRO or QIO in Arkansas, which has held the Medicare peer review contract for over 25 years.

In addition to its role as a Medicare peer review organization, it has done extensive work in the state for Medicaid working with their managed care program as well as now developing a program with critical access hospitals. So currently for the Arkansas Foundation, Medicare peer review is about 33 percent or 35 percent of the overall activities of the organization.

As mentioned earlier, the program has changed quite a bit over the last 10 years with the change to quality improvement activities. We are now involved more with population-based medicine rather than by case by case implicit review with all of those techniques, difficulties, and limitations. To accomplish this population-based approach we've had to increase and change that nature of our staffing.

Increasingly PROs have academic physicians like myself on board leading the quality improvement programs in

their states. We've also brought on a large cadre of statistically competent and epidemiologically oriented individuals to manage database techniques. We have become experts in clinical performance change as well as becoming expert in social marketing techniques, which is a new capacity of the organizations.

This fall the PRO program embarked on its sixth scope of work, which is an evolutionary change from the work beginning in 1992. During the fifth scope each PRO, for the most part, determined and selected areas of clinical focus and performance measures that they use locally to bring about collaborations. Many PROs have collaborated with over 50 percent of the acute care providers in their state. For example, in our state we generally have two-thirds to three-quarters of the hospitals in our state participating in a project.

This can often result in a clinically meaningful and statistically significant performance change. The problem, of course, for these local successes is you cannot aggregate them across states. So if you want to have a national assessment of the program, it would be difficult to

aggregate locally derived measures.

The sixth scope of work has now nationally standardized measures which gives the opportunity to do benchmarking locally to national data. You could then benchmark across the state, as well as gives you a chance to look at how states perform within the program and how the program as a whole performs. This is a major change and it will be an advantage to the program. There is still quite a bit of opportunity though for local projects as that is often a laboratory for future work and future national standard activities.

As Jeff Kang had mentioned, the sixth areas have been listed before you and are in your hand-outs and have been tested in a variety of scientific ways to standardize the measure.

The American Health Quality Association also believes that because of this expertise in becoming, if you will, a consultant to area facilities and hospitals in the achievement of quality improvement is increasingly the PROs are taking on a convener role or a partnership role in their

communities. We are increasingly working with hospitals, nursing facilities, physician offices, home health agencies, Medicare+Choice plans. Many institutions, many quality improvement experts in the states now view us as, if you will, a free resource and a convener for them to exchange professional ideas and concepts.

Practitioners and patients benefit from having these clinical topics addressed simultaneously in multiple settings. So now we're doing immunization programs, for example, as hospitals as well as in the outpatient offices. We're doing the heart attack project looking to improve the rate of beta blockade and aspirin, we're targeting physician offices as well as hospitals.

I'm pleased to tell you that our work in extending this kind of activity to the physician office has been remarkably well received. As a physician, I was a little nervous about sending out my first letter to offices and I got two unsigned hate letters out of the whole state, which really isn't too bad when you think about it. I expected, frankly, when I took on this role seven years ago, I expected a lot more conflict and, if you will, name-calling

and I got almost none.

DR. ROWE: Two is about a daily average actually in New York so that's not bad.

DR. GOLDEN: It's interesting, we now have when we send out a project to physician offices, we get back 150 responses from offices signing on to the project and stating that they're going to work on certain indicators which far exceeds my initial expectations for that kind of activity.

One of the things that I think helps besides the consultation role is there is, of course, the history of confidentiality in the program as well as in some of the plans the issue of antitrust protection. Plans can get together around a table with a PRO in ways that they couldn't do by themselves. That I think is another advantage to, if you will, the umbrella that the PRO can offer.

Given a function as a convener role, a partnership function, is that the PROs can help to simplify multiple quality measurement demands made by health plans, providers and practitioners upon them by accreditation organizations and government programs. Essentially, we can become a one-

stop shopping activity for collection of data and for reporting. Health care providers, especially physician offices now are bombarded with multiple data requests from third parties for similar information, and slightly different specifications.

They also receive slightly different and sometimes conflicting recommendations for clinical performance and changes in terms of quality standards. The QIOs are becoming more recognized as a source for a consistent message and one that they could follow as if you are a local expert in setting standards for them to try to achieve.

Basically, PROs possess the enhanced credibility for the dissemination of practice guidelines because we're also not associated with entities where the utilization issues directly benefit the financial status of the entity issuing the guidelines.

So basically this approach has been successful. Attached to the report to complement these comments are some data from our Arkansas foundation which shows some of the projects we have done, the number of participants and the data results. Many of these activities are now involved

with the national program and we're pleased to see that happen. The PROs are basically a penalty-free zone, if you will, where quality improvement can occur. Data for quality improvement in this kind of set up where it is confidential can spur improvement which has less defensiveness to it than some of the accountability measures where people become quite concerned about the precision of those measures.

That's kind of a snapshot of our activities. It's been a very exciting program to be a part of for the last seven years and I think we have a lot of opportunity to continue working with providers in our state to improve care to all of the Medicare beneficiaries.

DR. WILENSKY: I just want to comment that if you only got two hate letters, that's really quite extraordinary. When I was at HCFA and would go out and speak to physicians, the PROs in the early 1990s generated the most negative, and strongly negative responses, of the many things that physicians felt HCFA was doing to them and not for them. The PROs probably was at the top of the list. I think the change in orientation that started with the third or fourth scope of work of moving to an outcomes-based

and away from the retrospective case by case review has helped. But obviously there's been a very significant change in attitudes given the kind of experience that you have had relative to what was existing in the early 1990s.

DR. NEWHOUSE: A question really for all three of you. If you were engaged in a strategic planning effort for PROs, QIOs, where would you say they ought to be in 10 years?

DR. GOLDEN: It was interesting, the other day when I had to give my annual address to the AHQA house I had an old document from Dr. Jenks who five years ago gave a speech on what should the PRO be in five years, and actually all the points he made in that speech in Philadelphia were actually real and they had happened.

I think that the capacity for the PROs to serve as a community partner we are now, in our organization, increasingly working with the health department and organizations like the Arkansas Heart Association, Lung Association, Arkansas School Nursing Association, across multiple payer lines to serve as a neutral data collection site and educator to push quality standards, to advance that

agenda is an activity that you will achieve credibility over time.

I believe that we really have a capacity here to network with multiple agencies within the state to put together a rather effective coalition to achieve quality improvement across a broad range of sites by this kind of coalition building. So I think that we can be taking on more activities and achieve more by this additive process by coalition building.

DR. NEWHOUSE: Either of the other two want to comment on that?

DR. KANG: I think actually we're asking -- there's a very fundamental question here. Is quality and quality improvement, is competition the way that we're going to get there versus collaboration? I actually think it's a little of both. There are going to be places where, to the extent that competing providers are in full control of the measure or the performance, I think competition is a mechanism.

But there are going to be many places and quality, to the extent that the outcome is actually not completely in

control, and in reality it's in the control of the entire health care system and in the certain sense there, what you really want there is a collaborative approach. I think that in 10 years the PROs really ought to position themselves and ought to be the convener or the catalyst for that collaborative approach where collaboration is really desirable. That would be collaboration for both Medicare, Medicaid, and other payers.

So I think we do need to have both mechanisms and we need some wisdom to distinguish where competition is good for quality purposes, and I think the PROs really are going to be the collaborators and conveners in the country.

DR. NEWHOUSE: Let me turn to the issue that I'm sure others will have questions on too which is the program integrity, quality improvement interface. I think it was David Schulke that talked almost like a firewall within the organization between these two arms. I guess my question for you is, speak to the advantages of having them in one organization as opposed to just divorcing them into two organizations entirely.

MR. SCHULKE: First, a strict firewall is not

there. Cases could be generated, probably some cases will be generated as a result of activities in other areas than case review and payment error prevention. And that's if someone is found to be paid that shouldn't have been paid, I haven't found anybody in the hospital community and I've talked to hundreds of people in that community, who have been able to stand up and say, a hospital that was paid in error, was found after careful review to have been paid in error, should be permitted to keep trust fund dollars that were known to have been paid in error. So however that is discovered, that money should be sent back.

The firewall or the separation is useful, because these are very different kinds of activities --

DR. NEWHOUSE: No, I understand why -- the issue is why it shouldn't just be two different organizations.

MR. SCHULKE: I'll do this very quickly. I think that there -- I don't know who else Medicare can turn to at the moment that has this expertise, that can provides the safeguards for the providers as well as for the Medicare trust fund.

DR. KANG: If I could, there is a firewall and

it's deliberate. The firewall, quite frankly, is between the Department of Justice and the program integrity folks and the PROs. That's really where the firewall is. If you look at this activity, this activity is not about recoveries. This is about taking a payment error and taking a payment -- defining a payment error and then taking a quality improvement approach, working in a confidential environment, to actually improving that going forward.

The firewall really is, that activity doesn't lead to Department of Justice kinds of actions or whatever. That's really where -- so there is a firewall.

DR. NEWHOUSE: And the firewall is in statute? That is in statute?

DR. KANG: We are kind of -- the answer is mixed. There are some administrative things that we actually have to do to make sure that that continues. But the general concept of the PRO program is that their activities are statutorily protected.

DR. NEWHOUSE: In talking with the people in Massachusetts, they made the point to me that they would like to undertake demonstration activities or

experimentation activities but they feel precluded from doing that within the state because anything would have to be statewide. Do you have any views, or have you thought about giving the PROs some kind of demonstration authority?

DR. KANG: I think that's my question. The "demonstration authority" is in the extent of we do have task 2.1 allows for local projects. There is local flexibility and in fact those do not have to be statewide. So there is flexibility there. The one thing though, it's not a classic demonstration like a demonstration project you may be referring to in a sense that they cannot do payment kinds of --

DR. NEWHOUSE: They also think they have to -- if they've got something good it should be statewide, but maybe they're just misunderstanding.

DR. KANG: No, that is not the case at all.

DR. GOLDEN: With the performance-based contracting, you really -- if you don't do a statewide project you're probably making a mistake.

DR. NEWHOUSE: That's their point.

DR. GOLDEN: On the other hand, if you're doing

locally derived project you could begin by a pilot with smaller numbers of facilities. The evaluation process is different, so they're not going to be evaluated on the same kind of criteria for requiring statewide projects.

DR. ROWE: Two points, one on this. The payment error prevention plan, I think your comments are very interesting because I sort of get the impression that people think there's this firewall between HCFA or HHS or anything else and it's all contained in this confidential environment.

Mr. Schulke said that if the physicians weren't supervising it, he doesn't know who else would do it. I can introduce you to some representatives of the inspector general at the Department of Health and Human Services who have a great interest in this area and when they arrive, they arrive with a representative of the U.S. Attorneys Office. So I think we shouldn't make believe that the only payment error prevention activities that go on, go on within this program.

My question relates to something entirely different. Dr. Kang's presentation -- and he was an

outstanding trainee at Harvard Medical School.

DR. NEWHOUSE: Wrong medical school, I think, but right college.

DR. ROWE: Resident. He slipped and he said it was related to income. The facts are, unfortunately, that we know that in a given set of individuals with the same disease, socioeconomic status is a major predictor of functional status, disability, and outcome. I'm particularly interested in the sixth scope of work in the fact that there is this so-called DASPRO, the disadvantaged population PRO that's been developed. I think it would be important for us to hear a little bit about what the PROs are doing with respect to disadvantaged populations in terms of improving outcomes.

DR. KANG: First of all, I actually need to -- I think that to the extent that we get the true outcomes measurement based on functional status that the issue of risk adjustment or case mix adjustment is a real issue, or for example, for mortality rates, we have to be worried about that.

What we are talking about here though are clinical

processes where the denominator removes all those people where there are contraindications. So that the true, the correct -- the desired result is 100 percent on those clinical processes. So I think that's one way of dealing with the risk adjustment issue.

Now the second issue though that you're raising is, irrespective of that ought to be 100 percent, there are racial disparities. What we have asked the PROs to do is in each of their states is to identify any of those 22-some-odd indicators that David talked about, determine for a significant minority group if there is a racial disparity, and then actually ask them to reduce that disparity for 25 percent of the population in the state.

The reason for this is that many of the systematic interventions that we think about from a quality improvement standpoint work for the "majority population" but you may need to do the "extra mile for the minority population." I think that we view this as a mechanism to try and determine, are there other additional systematic interventions that need to occur for purposes of informing the seventh scope of work. So I think this really is a major effort on the

department's behalf to really try to encourage greater research in this area about what works for disadvantaged populations.

MR. SHEA: Jeff, I wonder if you could talk a little bit about the connection between the quality improvement of QIOs and beneficiaries being able to be more knowledgeable, make decisions, or at least understand the kind of care they're receiving. Specifically, I clearly see how there's an indirect benefit to beneficiaries due to quality improvement, if indeed it is successful, and the three of you talked very enthusiastically about what's going on and the potential of that.

But I wonder if there's any direct benefit, or is there some interface that's planned as a future stage. And behind the question is, I'm a little bit -- if there isn't, as kind of my sense here and maybe I'm just missing it. If there isn't, I'm a little bit perplexed by the centrality of this in HCFA's overall strategy. Because I've heard this presentation a number of times and I keep on thinking, but this is a plan that has all these beneficiaries to worry about, and where is that piece of it?

DR. KANG: I think that's a very legitimate question and I don't know if you recall that quality strategy. What you're really asking is the consumer information part of this. There's really three levels of information. There's information around plan choice. There's information around provider choice. And then once you've picked your providers, information around individual treatment choices.

I actually think that HCFA does have a very strong view that we need it, but the likely vehicle is going to be the Center for Beneficiary Services with Carol Cronin and there are funding issues here. The PRO really is set up for quality improvement efforts with the provider community, while we actually have user fees, et cetera, for the issues of consumer outreach and education.

So you've heard my presentation. It's -- largely because it's built around the PROs and the provider kind of interface. There is, I think, another presentation around the consumer information outreach. It's in a different part of the organization, but it is very important.

Now I do think, just to the extent that in any of

these clinical quality improvement areas there is a consumer message that ought to occur, there's no question that I think the PROs will get involved in that. But it is kind of secondary to trying to make the systematic interventions to improve the delivery system itself.

MR. SHEA: I'd comment that it seems to me that you're well-grounded, at least based on how you present this. I don't know much about the QIOs but I've heard a little bit. You're well-grounded in saying that this is a strong attempt with broad reach on professional improvements, clinical indicators, and so forth. I don't think there's much of a basis though for saying that that is a process that suits other parts of the equation; for instance, the payer question.

I don't know, Woody, what your experience from the Ford point of view would be, but my own experience in our purchasing activities is this is not -- people don't see this as, this is where the solution is going to come from.

DR. GOLDEN: I was going to say, one of the things that -- I don't know if this is what you're getting at. On the Medicaid side we're conducting CAHPS surveys, consumer

satisfaction surveys, and I think that HCFA has the Health of Seniors activities going on where there will be similar kinds of activities on the Medicare side. So there will be patient satisfaction, beneficiary satisfaction surveys being done to basically bring that back into the program. Is that the kind of question you're asking?

MR. SHEA: No.

DR. KANG: I think it's more where consumer outreach is at.

MR. SHEA: Or use by purchasers.

MR. SCHULKE: Let me respond to part of that. Congress wrote into the PRO statute that there has to be at least one, and in many states there's more than one, consumer member of the governing body of the PRO. And the purpose of doing that was to ensure that there would be information from the PRO going out to the consumer community, and information from the consumer community coming back to the PRO to invigorate their understanding of what was needed and what was not understood. So there has been an attempt to ensure that each of these organizations has a link to the consumer community.

Then following from that are a variety of patient education and complaint response and other kinds of services to the beneficiary population. This was part of the round of reforms that happened in the mid '80s.

On your question with regard to payers, I'm going to take a stab and see if I'm answering this. Some PROs have been very successful, and Dr. Golden alluded to this, in getting otherwise competing managed care organizations around the table to talk about how they will use the identical measures, and data elements, and timing, and so forth to conduct a statewide quality improvement initiative in, say, diabetes. That was the most common area where this was done. These plans would not otherwise have been found in the same room talking to each other in those tones.

In fact, the presence of a public purpose, an organization representing a statutory purpose in bringing them together helped ensure that they wouldn't be violating antitrust laws.

They in turn, by collaborating on that, did not drive the providers and practitioners nearly as crazy as they would have as if each of the plans had had its own

initiative in diabetes, looking different and asking for different data elements, different abstraction tools and so forth, and different feedback mechanisms on different schedules. So people in general have really liked that.

In Michigan, in fact, Ford actually kind of kicked this off, the PRO has been successful in working with a group of hospitals that were reporting to employers but weren't involved in the Medicare program. The employers heard about the Medicare quality improvement program. The employers learned about the quality improvement potential of that and talked to the hospitals about using the Medicare indicators as their indicators. The hospitals were happy. The employers were going to get good data. And the PROs will be able to work with those hospitals doing much more than supplying indicators. They do remeasurement. They do intervention strategies. And a lot more might be accomplished because everybody is around the same table working on this project.

The PRO did not have access to those institutions until the employer said to them, we care about these measures. We think the PRO has a good thing going and we

want to try it out.

DR. LEWERS: I've had a chance to discuss these issues with the gentlemen, but you said a couple things which stimulated me a little bit. Bill, I think you talked about credibility being built up over time, and that certainly is true. Credibility can be lost over time, except the time frame is a lot shorter. That's a major concern, as you know, that I have and we have. I would say that you didn't get but two letters because of what happened in the fourth and fifth scope of work.

My concern, and I know your concern, is that you have a penalty-free zone at this point, but how are you going to retain that with the PEP and the MIP programs and the reporting requirements which are required in some of those? And how are you going to maintain that credibility? I think the PROs have done a great job in the last few years. I think everybody has come to recognize that. But I see a great risk to you in losing that, and I can't help but take just a sidelight.

David, you said that money paid in error should be paid back. I don't think anyone agrees with that. But the

reverse is also true. Appropriate money that's not paid should be paid back as well.

DR. WILENSKY: Do you want to respond to that?

DR. KANG: Yes, I actually need to respond to that. First of all, the PROs do not do MIP. MIP is a completely --

DR. LAVE: What is MIP?

DR. KANG: MIP is the Medicare Integrity Program or our program safeguard. They do not do it. So that's the first.

The second thing is we did, based on comments, make a very important change with regard to the payment error rate. The payment error rate that we're holding PROs accountable for reducing is the absolute value of the overpayment plus the absolute value of the underpayment. So they are now equally incented to return underpayments. So we heard that issue loud and clear, and they equally incented to do that. So to the extent that they find an underpayment, this should go back also.

DR. LAVE: This is really a follow-up of Gerry's question. That is that as you were talking, it struck me

that in some cases you were on your own turf and in other areas that you were getting into areas that what might be called more competitive turf, and I was wondering if you might address that. For instance, you were talking about developing measures of appropriateness of care or something like this. The HEDIS is out there, and NCQA is out there, and I was curious about the extent to which in fact -- how these organizations work together and whether or not there is a struggle for turf as this area of quality improvement becomes so vital.

DR. GOLDEN: We're in a competitive economy and it often makes the country better. I'll give you some examples though. Many of the -- the PROs actually got in the business of performance measurement really early on, 1992, '93. Some of the things that we have done have been adopted by others, and there is no -- once you have a good quality measure it becomes, if you will, a public good. So I think people freely exchange.

Right now the Joint Commission is talking to our organization about using measures we submitted to them for ORICS to become core measures for ORICS. So which comes

first? I don't know. It's, I think, all to the better of the system.

Clearly there are some expertise involved. You worry about redundancy. I would say right now, a personal opinion is that the PROs have some of the more experienced individuals in the country in analyzing data and developing performance measures and making change that you'll find anyway because of the experience with the program.

DR. KANG: I think that, with regard to performance measures since this is an early science, there is this issue of let 100 flowers bloom. But at some point there needs to rise the standard core measures, and the PROs really are that vehicle that is, quite frankly, occurring. When you think about it, for example, we sit at NCQA on their HEDIS measures also. What we've done, they've now endorsed these diabetes quality improvement measures. We have picked them up in the PRO program as our diabetes performance measures.

What will quite frankly happen is that they'll be with all the providers now pushing these measures. That is, in a quality improvement context, the beginning of

standardization. So in this penalty-free and quality improvement context, people get familiar with the measures, what they mean, perfect the measures, what can we do with it? At some point that will end up being a mandatory measurement for accountability purposes and I think that the natural maturation of this process really is going to end up occurring in the PRO program.

DR. GOLDEN: Just also a follow-up comment. Quality improvement is not a straight line very often. If you wanted to graph it, it's almost like a sigmoid curve where if you have a very low performance there is often a very rapid increase with some activities to a certain level, then it flattens off again.

I think very often what's happening is the quality improvement piece is the steep part of the curve and when you get to around 70, 85, 90 percent of compliance, it flattens out and that's when you need accountability to get the final 10 percent because it's real tough to get the last 10 percent.

DR. MYERS: Maybe I can try a quick different version of Judy's question. What can or should or is the

relationship between the PROs and the newly renamed and increasingly funded Health Care Research and -- the AHCPR, the Health Care Research and Quality Agency?

Then the second piece of that is, the organization that's now being created as a result of the President's quality commission that Gail Warden has spearheaded that I now understand Ken Kizer is going to run, what is your relationship with that entity? What role will that entity play with you? Because I do think that there are a number of quality related entities that are being created and are growing, but I'm not sure there are the appropriate connections between them.

MR. SCHULKE: Let me answer this briefly. We sat down with the AHCPR, Dr. Golden convened a meeting between their leaders, Dr. Eisenberg and other senior staff, and HCFA, Dr. Kang and senior staff, and we all got together and talked about how these programs might be interdigitated, to use Margaret's earlier term. This is an important agenda for everybody because there's a lot of duplication and that's what Congress was saying when they authorized the new agency, the remake of the AHCPR.

The result of that first conversation was the AHCPR put out an RFA asking for entities to step forward that were working with quality improvement organizations, and they said quality improvement organizations/PROs, so that they could investigate which intervention strategies were the most promising and which would work the best. So their first attempt to put to work the synergies here we'll see shortly when they fund those projects.

The other thing is that we're supporting the effort with the forum and I hope that many of the PROs individually, and certainly the association will join the forum, become members of the forum and participate in the forum's quality improvement and health services research council, and hopefully elect somebody who has that kind of expertise to their board from that council. Councils get to elect people to the board.

Finally, just as an answer to both I think, the PRO community is sitting around the table with others in generating new measures and provides, for example, the SCRIP project which HCFA has convened with several other organizations through a grant of the JCAHO. AHQA is

represented there. PROs sit at that table, and they're helping develop measures of pharmacotherapy that are clinically, and in terms of facility of gathering the data, measurability of data, these would be robust measures.

We're at those tables trying to ensure that the practical application of measures is considered at the same time as their clinical relevance.

DR. GOLDEN: Let me follow up. The agency can fund the raw material for quality improvement activity, which is to say the evidence that generates the ability to create measures. So the evidence-based centers, which systematically looks at literature, helps us determine what we can create measures with. Some of the research to look at what is effective is very important.

The guidelines clearinghouse is important also, as a mechanism of finding raw material to create measures.

And also, PROs are increasingly involved with grants, working with academic centers funded by the agency to look at more techniques to improve quality in the community.

DR. WILENSKY: Can you tell me, David, whether the

changes that were referenced to AHCPR have actually been finalized and passed in statute? Or are these still being considered by both houses?

MR. SCHULKE: Greg, is it signed by the President yet?

VOICE: No.

MR. SCHULKE: We have the conference committee which has only, I think, report language to resolve as difference. And some of the report language speaks to the issue of their operational role, or lack thereof.

DR. KANG: This is maybe a separate discussion, but just quickly in terms of, probably the more important question with regard to the National Forum on Health Care Quality Measurement and Reporting is what HCFA's role is. HCFA actually is a member there. We are there under a statutory piece that's called the National Technology Transfer Act, which allows federal agencies to actually sit on these standard setting boards with the assumption that whatever standards they come up with, with regard to measurement standards, would be actually adopted by the programs.

Now that's a conditional assumption. The actual standard setting body needs to engage in a consensus essentially rulemaking kind of process, which is a broad-based umbrella representative of all stakeholders with an appeals process, et cetera.

The presumption, though, is if the forum as a standard setting body comes up with here's the standard way of measuring mammography rates or whatever it is, HCFA then would adopt that for its programs.

A similar model is the SEC's FASB model. The SEC sets standards for public capital markets but the reality is FASB is a private sector with all the accounting firms sitting there. They come up with it, SEC adopts it, and they rarely -- while they retain their statutory prerogative to differ, they rarely differ if the actual process itself is sound and inclusive.

So I think the forum, quite frankly, is positioned, if it is sound and inclusive, it is positioned now as the national standardizing body for performance measurement and HCFA would look towards really to adopt performance measures.

DR. WILENSKY: Thank you very much. We appreciate the amount of time you were willing to give us.

We will recess until 1:30. Commissioners, lunch is outside.

[Whereupon, at 12:47 p.m., the meeting was recessed, to reconvene at 1:30 p.m., this same day.]

AFTERNOON SESSION [1:46 p.m.]

DR. WILENSKY: Can we please get started? Helaine?

MS. FINGOLD: Good afternoon. We're continuing our discussion on quality assurance and improvement for Medicare beneficiaries. This morning we had two panels, one focusing on quality assurance through survey and certification; the second focusing on the work of the peer review organizations under the sixth scope of work.

What I'm going to try and do here is just briefly go through a little bit of the background of what was in the paper and just the nature of the projects that the staff is thinking we could pursue.

What we really want from the commissioners in this session is guidance, as to where you'd like us to go with these issues. There's a very broad range of topics covered in the paper and covered this morning, certainly, in the two panels. I don't think we could realistically cover all of the issues that are raised. We'd like to know where your particular interests lie, where you think we could focus and have the most impact.

So that's really the goal of the session.

Just to raise some of the issues that are discussed in the paper and are sort of in the outside world about the survey and certification process, there are criticisms and issues raised about the conditions of participation, specifically that they're not current.

And again, people mentioned that this morning. It's difficult under the regulatory process to keep up with the state of the art. There's a question again of consistency of the conditions across facilities. How are different things treated in context of maybe hospital COPs versus SNF COPs. These are some of the questions that get raised.

Then further, there's a question of how consistent are the COPs with private sector standards, the accreditation standards.

We thought that we could address some of those issues. If you're interested we could do comparisons of COPs across facilities or with the private sector accreditation standards, and research and compare to get a sense of how these things are comparable or not comparable.

There's also issues around the enforcement of these standards, on both the state survey agency and the private accreditor side. Again, you heard a lot about the budgetary issues that relate to states have different priorities in implementing the standards, some of those are budgetary driven. Some of those are just internal to the states, different states have different licensing laws so their focuses are on different facilities.

For example, and I think this was raised in the paper, some states don't license ESRD facilities. So to the extent that there's not enough funding, or that there's a lack of funding on the Medicare certification side, if there's no licensing process in the state for a facility, then they're not getting oversight from the state level, they're not getting as much oversight on the HCFA side. So there's sort of a gap that rises there.

There are questions about the roles of private accreditors and whether they have a conflict of interest inherent in the work they do. Again, we heard they're often cooperative, they're cooperative projects with the facilities. They see themselves as educators. What about

their role? They have a regulatory role of sorts in their relationship with HCFA, and how do those two things play out?

Funding is a big question. Again, that was raised, HCFA apparently is taking a hard look at its funding, at the funding process for survey and certification. That's something we could take a closer look at.

Again, the states and how they are addressed, how they participate in the funding process. Again, the focus between long-term care and non-long-term care facilities and how political issues seem to affect these things.

Just to give you some context, the FY 2000 budget request for survey and certification, I believe Rachel said it was approximately $200 million for all related types of activities. My understanding was just for the survey piece it's about $168 million. $121 million of that goes to long-term care facilities and $47 million goes to non-long-term care.

The PRO program has really evolved, as you heard discussed by Jeff and the panelists from AHQA. From case

review to local quality improvement to nationally coordinated projects. It seems like it's come very far.

The survey and certification process hasn't really received as much attention and scrutiny as the PRO program has. It's a range of new projects. The sixth scope is outlined on the slide.

Some of the questions that were discussed this morning deal with the payment error prevention program. Again, this is a question of the role of the PRO and how that's being implemented.

We could investigate or research HCFA's review of PRO activities, how the PROs are being held accountable for their performance at the state level, and how the lessons learned by the PROs are actually incorporated into the program to get a better sense of that. Again, that was a question I think Gerry was raising.

How is this affecting the consumers? How is this affecting the beneficiaries?

The funding on the PRO side is determined on the three year -- for the three year sixth scope of work, it's approximately $840 million. That includes not only the PRO

contracts but supporting contracts, so like data related things. That again is the three year total.

That money doesn't come out of the appropriation. Survey and certification is funded out of appropriations. PROs are funded from the trust fund dollars. So there's a very different process that we could look closer at if you'd be interested.

Finally, the question of coordinating the quality assurance/quality improvement efforts. Are the goals compatible, the PROs and the survey and cert goals? Should they work together? Can they work together? Are there any barriers to their cooperation? Some of those issues involve data exchange. How much data can go from one to the other and what are the implications of that?

Essentially, we just want your feedback, so I'll just leave it at that.

MS. ROSENBLATT: Coming from someone who doesn't know too much about this, first of all, thanks for writing this stuff well and arranging for the panels.

I was just struck by how old the conditions of participation were. I think that if you could somehow

prioritize that in the work effort, that seemed to me to be a real need.

DR. LONG: I don't know if we could actually influence this at all, but I certainly don't understand, at this point, either the history or the politics of having these very disparate mechanisms for the funding. Some things are the vagaries of annual appropriations and other things have at least the semi-permanence of trust fund basis. In the sense of overall program integrity, my naive perception is that logically it ought to be a trust fund responsibility. But I'd certainly like to know more about that issue.

DR. WILENSKY: Let me raise a question. I thought the information that you provided through the paper, which I thought was a very good summary of the issues, and also the panels that we heard from, raised a lot of interesting points and interesting issues. But when you talked about some of the suggestions for future work, I think this may be building on what you just said.

I think that it would be more useful for us to try to step back and provide more philosophical discussions

about what we think would be appropriate ways to integrate the various activities. What would be appropriate in terms of standards in a broad sense across the board, rather than looking at more technical issues which really seemed to me to be HCFA's purview and not something where we really either bring expertise nor do we want to duplicate their efforts.

And so, in terms of looking at some of the mechanisms for overseeing state licensing agencies and deeming to see that they are consistent with the goals, that seems to me to be getting very narrow and specific, and something that we ought to basically turn back to HCFA.

But the issues that are raised about deeming and consistency and general appropriateness of resources set aside for these areas, the issues of process versus outcomes. Mary and Woody both raised questions about staffing ratios which tend to make this particular economist very uneasy about putting into statute or regulatory requirements staffing ratios that may well reflect some past year's way of doing something, as opposed to having strategies that look at outcomes.

And when you see troubling outcomes and work backwards to see whether or not there are problems with regard to the particular combinations of input and processes that some places have chosen to adopt rather than to say every single structure must have six of that and seven of something else and 14 of a third type. It really doesn't seem to be very helpful.

But it struck me that the very interesting series of issues that you have raised in the front part of the discussion that our scope of work really ought to be to try to provide some thoughtful comment about how these relate to the other chapters that we do on quality and outcomes, rather than to focus on these very narrow technical issues where I don't really we think we bring much to the table. And besides, it strikes me much more somebody else's problem and scope of work.

So I don't know whether others feel that way, but the general walk-away comment that I had was that.

DR. WAKEFIELD: Gail, could I just comment on the staffing ratios? I want to make sure that what I said wasn't misunderstood. I was using it as an case in point,

as an example that some states now are wrestling with this issue of staffing, not to suggest that I personally feel that that is the road to go.

As a matter of fact, on an IOM committee that I serve on, just last week I was basically advocating against it at this point in time. But rather to say that that's an indicator, one indicator, along with the data that I presented from this risk management company, to suggest that something is going on in the organization and delivery of that care that's potentially quality can be compromised. It might be related to the staffing mix, but whether or not you come in and regulate the staffing for facilities, I'm not on board that ship yet.

DR. WILENSKY: But it strikes me is that what we can really bring are these broader discussions as opposed to getting, I believe, into some of the very narrow issues which are HCFA's purview by statute. I'm not sure that we bring an expertise to the table on that. Again, this is just my reaction to that.

DR. KEMPER: My reaction was similar, and actually wondered if we could do something on data for monitoring

quality and how that might be used in an effort to improve quality in the fee-for-service side, particularly some of the data that are starting to become available from MDS and OASIS, to think a little bit about broader quality improvement efforts.

I guess in that regard, I wondered if you could comment on how this year's work plan relates to the work we did last year and the chapter we did last year, which had some fairly I thought provocative ideas about where to go and assuring quality. I guess it's related, it's quite some distance from there to conditions of participation, and so on.

MS. DOCTEUR: Last year you ended up with one chapter that provided what I thought of as sort of a framework for thinking about what sorts of structures and processes needed to be in place or were currently in place or were being developed in HCFA to assure and improve safeguard quality and to empower consumers to address quality. You looked very broadly at what exists now and what might exist in the future in fee-for-service and managed care, and made some recommendations designed to try

to equalize attention being paid. That was a very broad chapter.

In addition, you had chapters on errors, of course, in consumer information.

This year our thinking about how to proceed in the workplan reflects some commissioners' comments that while they thought that work was useful, there was some real interest in getting down to some of the more specifics and being able to make some more very specific detailed recommendations about improving quality in certain areas.

To that end, we're trying to bring you work first that's focused on quality improvement and assurance systems in two specific service sectors, end-stage renal disease which you'll hear about this afternoon, and the post-acute care arena which you'll hear about at your next November meeting.

Helaine's work here is designed to address some questions that were raised at your retreat this summer regarding what has happened on the PRO scope of work and some very dramatic changes that have been underway recently. So that was designed to bring you some information.

And also, the survey and cert process which has been subject to a great deal of policy interest recently, with some recent reports that have been issued.

So we wanted to bring you up to date with this information and to see whether you were interested in pursuing some of the policy issues that have been raised, with an idea to making some recommendations. So that's where we've been and where we're going.

DR. KEMPER: That's really helpful. Just one thing on the more specific level, is this notion of targeting and the fact that you don't need 100 percent survey in one sector, and in the other sectors I don't know whether 10 or 15 percent is too low. But whatever it is, you could benefit from having some measures to target where that's done. I guess that happens at the state level, but some thought about that might be useful.

DR. MYERS: I wanted to bring up just a couple of thoughts for you to consider as you move forward with this area. I, too, thought the material was well done.

One, we've heard this morning some comments regarding the lack of intermediate sanctions, the lack of

availability of intermediate sanctions. I'm wondering whether or not there ought to be some consideration to what the pros and cons might be.

I think that with respect to the question of staffing ratios, that we seemed to get back on here a minute ago, that staffing ratios don't necessarily need to be a requirement. They can be used in those situations where there is an indication that there is a problem that results from them. And they could be, for instance, an intermediate sanction imposed upon a facility that's failed to demonstrate quality of care in a proper way for a period of time.

So there are a variety of ways to think about staffing ratios, and that might be one area that they could be used.

The second part I'd like to ask us to think about as well is the role of the public in oversight and quality issues. How does the public want to eat its quality information? Is the web site that we heard about the right way? Are there better ways for the public to get easy access to the information about quality? And what role does

the public have in providing reinforcement of high quality or information on suspected low quality? And what their seeing with respect to their loved ones that are in facilities. And how might we improve their ability to have input into that?

So I would ask you to consider possibilities outside of just the PROs and the entities that you've got listed in the paper.

MR. SHEA: Two suggestions for high priority in terms of the work, given resources. One is, I would suggest we look at the quality assurance end of the spectrum, not the quality improvement, in general. Because I think what's happened here, and was illustrated by the first panel, is that there has been a major move towards quality improvement mechanisms, the Joint Commission changes, and I think to good effect, Jack's comments are ones I think you'd hear from providers around the country.

But I'm afraid in the process that we've lost the question of who is assuring the public that the basic standards are being met here, when you look at the patient safety issues and so forth. I think there's a big

disconnect.

And I thought it was very revealing, Rachel at one point said about the survey and certification process as being a regulatory process and they do that through state agencies or through the deemed status arrangement.

The Joint Commission does not consider itself a regulatory body. In fact, they bristle at the idea. They are much more comfortable with the quality improvement and that's where their efforts have gone.

So this is a big disconnect, I think.

MS. FINGOLD: And that was highlighted in the IG report.

MR. SHEA: Precisely. That was the point we were getting to at the end of the discussion. So that's the first thing.

The second thing, this is a little bit contrary to what I just said, but if there were time, I think Woody's point is an excellent one about what is the interface between consumer use and all of this data that's being developed? Or is there one? I happen to think there is if we just push it hard enough here, and that we're beginning

to see some developments in it.

Those are the two things. And since other people have spoken on staffing, I'll just say on behalf of the harried nurses who we often talk about when we have our productivity discussions, I think we ought to do something about the staffing situation.

DR. NEWHOUSE: Here's some assorted reactions. One is, I learned quite a bit from reading this. This was kind of a dusty corner that I never knew much about. I thought just actually putting this out there in a more accessible form was probably a service. Some of it seemed kind of self-evident, that if we were only updating these things, however infrequently we were, that somebody ought to take a look at it.

One more specific thing that occurred to me was whether there was any way to think about differences in the survey cert function across the sectors. I mean, obviously we heard about the long-term care rest of the area distinction. But it wasn't obvious to me that the survey cert for the same amount of resources in the facility would work equally well across different types of facilities.

Maybe it would, but I thought maybe somebody who knew more about this area than I could think about that.

I, at least, continue to have big misgivings about putting the enforcement function together with the quality improvement function in the same agency. I just think that's an invitation to trouble.

DR. ROWE: Why? That's the second time you've said that. It doesn't seem right to me either, but --

DR. NEWHOUSE: Well, in the improvement agency you want -- well, all of this discussion about the penalty free zone and reporting. Otherwise, you'll just get concealment of errors, mistakes, et cetera, et cetera, if the same person that's doing the quality improvement is doing the regulation.

I mean, that was what I took from all of the discussions about reporting near misses to NASA of all places, instead of the FAA. I mean, I don't know that it made any difference if it was NASA, but it was not the FAA. That seems right, feels right.

DR. ROWE: We have the same problem in the institutions because we have major interests. We, Dr. Loop

and us, all of us, have a major interest in reducing error and increasing safety and there's a major initiative around the country. Dr. Kizer had one in the VA and there's a lot of interest in this and some interesting work. Dr. Lucien Leap and his colleagues.

But in order to reduce errors, we have to detect them. And the same people in the institutions that are detecting them or reporting them are at risk for being criticized or punished for having made the errors. And so it's very --

DR. WILENSKY: That's the point.

DR. ROWE: And I just wanted to make that clear. That's a very significant problem not only to the agency, but it's also a significant problem for the institution that's providing the care. Unless you had another whole structure of people who were monitors or something, and we can't afford that.

DR. NEWHOUSE: I don't know what to do about the intra-institutional problem.

DR. ROWE: You must have the same problem, right?

DR. LOOP: We have the same problem. Our problem

in all these quality assurance measures is, of course, the cost of mining out the data. The cost of quality assurance is one area of resistance that you get from hospital administrators, is that it costs a lot of money to mine out the data. Jack's right on target.

DR. NEWHOUSE: I don't have an answer for you, Jack, but this would seem to compound the problem.

DR. ROWE: We have a problem on both sides. We have the problem at the agency side and in the institution. I'm just looking for some advice.

DR. WILENSKY: This strikes me, the direction that would be more useful for us to go would be to have discussions of these issues, as opposed to going on to the various specifics of looking at monitoring details with regard to state certification and surveys, et cetera.

I think these are exactly the areas that maybe we won't end up having anything useful to say, but to the extent that we can try to think about these issues and come up with various strategies, this is an area that is not specifically handled by other agencies. So I would encourage us to focus on thoughtful discussions of how to

try to account for these conflicting areas, objectives.

DR. NEWHOUSE: The third area I'd bring up, this really stimulated by Woody's remarks about consumer information. Woody in Michigan and I in Massachusetts have both been involved with surveys of hospitals to get at so-called patient reports, or the Picker surveys. These are not satisfaction surveys because they try to get patients to report objective things that could relate to the quality of care, such as were you told about possible side effects upon discharge? What kind of follow up?

Were you told what signs you should look for, that you should come back and seek care? How fast did the pain medication get to your bedside? If you wanted emotional support was it available? Things that, in general, it's felt patients can report about, as opposed to more technical quality of care.

There's actually quite nationally these surveys have been done, the last I knew of, in 300-some hospitals. There's quite a range in performance on these measures. While those wouldn't necessarily be decisive in any kind of choice, these have been publicly released in Massachusetts,

the scores for each hospital. It seems to have generated a considerable effort at improvement on these scores on the part of the hospitals.

We'll see, because we're going to do a re-survey next year, but certainly hospitals are reporting that they're undertaking efforts to change these things.

This goes obviously beyond Medicare but it seems to me, if we're talking about making information available to consumers, some kind of what is the patient's experience in the hospital, as opposed to our more traditional process measures of care, would be a useful adjunct.

DR. LAVE: Some of these comments overlap a little bit. I like the idea of looking at the general issues. The subsequent remarks are sort of being driven by my one experience in this, which was the nursing home one. That has to do with, again, the issue of deemed versus accreditation standard and whether or not that ought to vary by the type of institution.

The second issue is a different type of a consumer related issue, and that is how the patients who are most impacted by what's going on are involved in the quality

improvement processes. I think that one of the reasons I think it became so important for the nursing homes is people live in those nursing homes. So they're in this environment forever.

There are other environments for which this is true. The hospice center, the ESRD, they're somewhat different from clinical labs where you would bring people in.

So this is another variation on the patients, but I do think that the patients or consumers or clients, whatever you call these people, have a lot to tell about what is important to them. I just don't know how they are used in this process, so as we're reviewing this I think that is something, in fact, to take into consideration.

I think that the relative emphasis on quality assurance versus quality improvement is again another issue, because it's very important how the Institute of Medicine studies really totally change the way we want to think about it. It may all be to the good. I don't know. Maybe the emphasis on quality assurance was wrong and quality improvement is right. But there probably is a balance and I

think some idea of what that balance should look like.

And maybe whether or not that's a more important balance for different types of care systems. I mean, you may not say the same thing for hospitals that you would say for nursing homes, or that you would say for things where the person is in a less protected environment. The hospital is a pretty protected environment. When you're in your own home, that's not a very protected environment. Just a couple of thoughts.

MR. MacBAIN: Just to follow up on what Gerry was saying, in terms of the means of delivering information, but also considering who the audience for quality information is and whether the content is appropriate for the audience. We were talking earlier about nursing homes, where the audience is probably the family of the beneficiary and they get any kind of information that's useful to them.

Whereas, for acute care, the critical audience may well be physicians and are they getting information that they can act on? I remember vaguely there was a study about whether physicians were using the kind of information that New York or Pennsylvania reported and it didn't seem to be

having any impact on referral patterns either, so it's just that sense of it's not just the beneficiaries, but there are also key surrogates who have a lot of influence over how quality information is used.

MS. RAPHAEL: I agree with taking a more conceptual and broader approach. I think the main issue for me is even if you look at quality assurance, if you do a survey once a year which was the best, the nursing homes might get surveyed once a year and others might get surveyed once every 10 years. To me, from the point of view of the Medicare program, how do you assure quality when you're only coming in two days and there are 363 other days?

So you have to look at the system, to me, in a broader way. That means, to me, how do you make an institution value quality and want to institute quality itself? And what are the rewards for doing that? Because one is making sure you are at the minimum. But more importantly, is how do you raise the bar? How do you make sure that in five years overall the level of quality is higher for the dollars expended on all these different efforts?

Right now payments are not, as far as I can see, at all attached to quality. We've talked about this in some other venues. So that there is no reward for really doing more than you're required to do, for exceeding the conditions for participation, for really investing in better outcomes. So there has to be some way of looking at all of that.

I also agree, I think it was Joe who made the point, that we need to look at this differently for different sectors of health care. I don't think there is one sort of broad-brush approach that will work. When there were problems with home health care quality, one of the main issues was how low the entry requirements were, that you basically could be licensed in the course of a day or two.

So I think that we do have to look at it sector by sector and what will work in nursing homes might not be the right approach for the other parts of the system.

DR. WILENSKY: I think we ought to go on. We're about 20 minutes behind. Do you have enough sense of how to proceed?

MS. FINGOLD: We have a few things and we can come

back for additional information.

DR. LAVE: I just wanted to say that I had the same concern that Joe had and I think other people did about putting the error thing into the PROs. Here you're going down, quality improvement, quality improvement, quality improvement, and then errors. It just struck me a being very discordant. I thought that Joe's question was terrific.

DR. WILENSKY: I think this is really the direction we'd like to see this area go.

DR. LAVE: I'd like to make sure that that really is in there and see how other people feel about it.

DR. WILENSKY: If we can be sure that each of the presenters limits their comments to 10 minutes apiece, so that we'll have adequate time for discussion.

MS. RAY: Your last panel of the day is on quality assurance and quality improvement activities in the end-stage renal disease program. The first speaker will be Louis Diamond, who is with the MEDSTAT Group and is a nephrologist and active in numerous renal associations. He will give us a broad perspective on QA/QI activities in

ESRD.

Our next speaker will be Dr. Derrick Latos, who is representing the Forum of ESRD Networks, who is also a nephrologist. He will speak more specifically about the role of the networks on quality improvement and quality assurance.

Our last two speakers, Wayne Nix represents the National Kidney Foundation, Family Patient Council. John Newmann is from health Policy Research and Analysis. They both represent the consumer perspective, both being end-stage renal disease patients.

DR. WILENSKY: Thank you. Welcome.

DR. DIAMOND: Thank you very much. I appreciate the opportunity of being here. I have submitted written comments and, in fact, have resubmitted them again today. In the interests of quality assurance and quality improvement, there was a system problem in my office. And in addition, I take responsibility for the first submission.

I will not read my comments. They are for you to review and they are on the record. But I did want to make a couple of introductory comments.

Firstly, I have listed my various affiliations in the very first paragraph, but today I'm representing myself and I feel rather free to do that, and it's an exciting opportunity.

Secondly, the program lists me as a Ph.D. and MPH and I am neither of those. I am a simple physician, nephrologist and general internist.

And a final disclosure, given that it's just after lunch. I am from Washington. I live in the Washington metropolitan area, and this is not meant to be a partisan comment but I, in fact, have not used drugs in the last 24 hours. If you want, it could be the last week.

I'm going to share with you an overview, a framework for thinking about a quality measurement and improvement program in the end-stage renal disease program. I'm going to briefly describe for you, but not spend a lot of time, my personal assessment of the current state of quality assessment and improvement in the end-stage renal disease program, and will be spending the bulk of my time just sharing with you a couple of high level recommendations for your consideration about what steps you can take,

MedPAC.

I will tell you up front that I am offering in my written comments a bleak view of the current state. And again in the interest of quality improvement, I want to commend Jeff Kang and his staff at HCFA for the work that they do under considerable pressure and restraints.

The bleakness of my personal assessment is, in part, part of my nature, although I am an optimist. But I'm very much involved, in my daily life, in quality measurement and quality improvement. I see significant problems with what we are currently doing and the lack of a plan going forward.

I also see significant opportunities, which is another reason for "articulating" the bleakness of the current state.

Thirdly, it is self-evident that we have a vulnerable patient population that are being served in the end-stage renal disease program, so it's more incumbent upon us and society to provide the kind of measurement and quality improvement infrastructure and quality assurance program.

And finally, the notion that, in fact, we have significant elements of the program in place, including the existence of the networks, provides us this added opportunity for dealing with the current gap that it is my judgment that is occurring in the end-stage renal disease program, in regard to quality measurement and quality improvement.

So let me start by just sharing with you this diagram, which was not displayed in the Presidential Advisory Commission on Consumer Protection and Quality in the Health Care Industry. What I did was extract what I believe, at least, to be the major elements of a quality agenda. And I believe that these are applicable to all programs and to the end-stage renal disease program in particular.

The elements are displayed for you, and you've got this in your handout. I'd just highlight a couple of points, if I could. Number one, there are multiple elements and there's no easy fix to putting in place a quality measurement and quality improvement program. Each of these elements is important.

Secondly, there are some arrows that are connecting these various elements, as you can see in the overhead and in your handout. The connections are important. These are all connected. I may not have included all the arrows that are needed and all the connecting points.

What is not shown in this diagram, but could be articulated, is the sequence of how we implement these various components, because there are sequencing issues that need to be dealt with. That gets into much more detail than I think we want to get into today.

So let me just leave that with you because I believe that following that road map and committing to some of those elements in a planned and organized way would serve the end-stage renal disease well. And I think that MedPAC can provide some leadership for the community and for HCFA in particular.

The second section of my written presentation is an assessment of the state of the quality measurement and quality improvement program in the end-stage renal disease program. You have before the diagram, the side-by-side

which is a scoring system that I put together. It's pure judgment on my part and, in part, is being a little provocative. But again, I've shared with you some of the reasons why I take a reasonably bleak view of what is going on.

So let me close then, in the last four minutes or so that I have set aside here, for some high level recommendations for your consideration. Firstly, I think that encouraging HCFA and the private sector to further enhance the building of an information infrastructure and all its components is going to be essential going forward.

I specifically want to highlight the issue of facilitating the linkage of patients to the dialysis facilities and the dialysis facilities to patients and to physicians and vice versa. This would fundamentally change the kinds of interactions that are possible for patients who are chronically ill.

Related to that, implementing in a dialysis unit some point of care decision support tools that would facilitate avoiding some of the errors in medicine, such as drug-drug interactions and dosing issues -- and you had some

discussion earlier about that -- is eminently feasible within a dialysis unit, given the way it is structured.

Secondly, I think it's going to be imperative going forward that we expand on the current measure of performance measurement system that is currently on the agenda. As you know, there is significant work going on and you've heard about that and you'll probably hear it a little later today, about the conversion of DOQI guidelines into performance measures, the NKF clinical practice guidelines, and the core indicator project.

These are all very much focused on the dialysis procedure. The patients with end-stage renal disease have co-morbid conditions. They have hypertension. They have diabetes. They have coronary artery disease. And they have the need for preventive care and we're only doing a little bit of work in that area.

There is no reason why we ought not to be expanding the measurement system for quality measurement and quality improvement into those areas.

In addition, an adverse event reporting system needs to be vigorously explored and could be embraced under

a quality measurement system. Hopefully, the IOM's report that is due shortly will help us focus on how that can be done.

Thirdly, we've got some significant problems in engaging patients in their care. We don't have a national initiative to survey patients, as far as I know. There are sporadic efforts in the private sector. The provision of information to patients to facilitate their decision making, both clinical decision making as well as choices of providers and others, is rudimentary best. The current effort needs to be expanded and we need to look more carefully at what kind of information we ought to be providing before we rush off and provide that kind of information.

Fourthly, given the structure of the end-stage renal disease program and the current significant presence of the private sector delivery system -- I don't mean only physicians, I mean the dialysis chains, the need for partnerships between the public and private sector is imperative. And again, I think that this is something that MedPAC could focus on.

Fifthly, the quality measurement and improvement program currently under the networks is essentially funded only by HCFA and the Congressional mandate that requires that. The Medicaid program provides no funding for their activity, nor does the private sector. I think this needs to be looked at significantly. You know better than I what the percent of patients are that are currently in the program, including the private sector patients who are covered by Medicare as secondary payer for the first 30 months.

Putting together an integrated program with more innovative funding sources would be something that needs to be explored.

You have spoken before about research and there are serious gaps in the research funding in nephrology, in general, in my judgment, and in end-stage renal disease in particular, to the extent that the majority of the current research funding is directed at NIH, NIDDK type research. The translation of our findings into practice is not being vigorously explored and there are great opportunities here for doing that.

Finally, the development of a plan with incremental implementation is something that this commission could pursue with some vigor.

I thank you for your time. I'm about 30 seconds over time. Thank you.

DR. WILENSKY: Dr. Latos?

DR. LATOS: Good afternoon, Dr. Wilensky, and other members of the Commission. As Dr. Diamond has pointed out, some of us do better than others in terms of putting hard data together in terms of quality improvement. I apologize for the typo on the front of the handout that I've provided for you. I recognize this is a commission and not a committee, and I recognize that that was my error, not my secretary's.

I have provided written testimony for the commission today and I will not read verbatim what's in there. I think much of what I have described in that paper actually has already been presented in part by Dr. Diamond, not because we're sitting together but I think many of us in the community that have been practicing nephrology for 20-plus years recognize and parallel that some of the issues

that are really before us as challenges and opportunities, we've been talking about for a long time. So there will be some parallels, I think, in what I'm going to say.

I think it's important to recognize a little bit about what I'm going to talk about has to do with the network structure that we currently see ourselves working with. There's a background that's relevant, I think, to just review very briefly.

The original network coordinating councils were established in 1976. The purpose or the charge for the original councils was to assure effective and efficient administration of the benefits ascribed to the ESRD beneficiaries.

There were two bullet points, and I actually read the original that this came from. One had to do with developing the criteria and standards relating to quality and appropriateness of patient care. The second, that stands out for today's discussion, was to identify facilities and providers that were not cooperating toward meeting network goals and assisting facilities in doing the right thing.

At the beginning, many of these initiatives were really focused on having patients select the proper modality of care. The initial days were really centered in trying to get facilities and networks to get the infrastructure put into place to collect data, let alone begin to analyze it.

But things changed and in 1986 those original 32 network councils were restructured into what we currently have as 18 ESRD network organizations. I think that has given us an opportunity to really change the structure because that's exactly what's happened, not just in structuring, but the purpose of the network organizations in the last 10-plus years has really been to assist providers, dialysis facilities, and the staff who work in them, in the techniques of really analyzing and examining what they're doing, and I refer to the techniques of quality improvement.

It's been a real challenge to take a group of providers, physicians included, who really had very little basic training in how to measure what we do. Dialysis units are unique in the health care sector because we deal often with population medicine, unlike the one-on-one encounters that most cardiologists and family practitioners deal with

in their day-to-day activities. Nephrologists and their staff really have an opportunity to see what kinds of decisions they make not on a one-on-one, but actually for the entire population that they care for.

So being able to examine patterns of care really gives us a chance to make some definite improvements, and we have seen that.

I'm going to focus on some key areas that have been posed to me to deliberate for you. One of those has to do with the role of the networks in this thing called quality assurance and quality improvement.

It's very important to recognize that the networks have been designed to really focus not on the quality assurance piece, the external review so much, as one of focusing on quality improvement methodologies.

There's a very different approach. You know this certainly better than most of us do. We'll talk more about that a little bit later, but I believe that both these links are essential for the appropriate and quality oversight program that has to be in place.

Networks have, in fact, focused, to a large

degree, on quality improvement. Certainly over the last 10 years we've seen that. But that doesn't mean that the external oversight necessary has not been in place. In fact, there are agencies at the state survey office and to some degree the PROs that have been providing a very solid oversight to make sure that facilities are properly licensed, that they are meeting minimum standards, however those are to be determined.

There are some gaps, as Dr. Diamond pointed out, in what we need to be doing to assure not only that we continue to improve at all levels, but that no one who is receiving care in these facilities, is going to be receiving inappropriate care, particularly as patient safety is concerned.

A second area has to do with the proposed scope of work that the networks are going to be working in. The new scope of work has not yet been fully completed, so we don't know for sure what the networks are going to be doing, except across the board I believe that the networks envision a much greater component of quality improvement activities. The patterns of projects that have been examined to date

have been somewhat limited, and I think that across the nation there are opportunities to enhance the kinds of things that we need to be looking at.

Networks are regional in nature and problems are often regional in nature. While there is an important issue of trying to get some basic generalized quality improvement projects underway, there are areas that the networks need to be working directly with the facilities in their regions and focus on areas that are of local importance.

The bottom line to that is that we certainly expect that with more and more involvement in assisting the facilities in doing the right kind of quality improvement, that's definitely going to translate into improvements in patient care.

The networks, I believe, have enjoyed a strong relationship with HCFA. As you're aware, each network organization has a contractual obligation to HCFA. The networks are independent contractors and have very specific deliverables that must be provided and must be met. But there are some other areas that I think warrant some discussion.

I won't elaborate on them, because I've done that in the written paper, but the two that Dr. Diamond pointed out, the core indicators project and more recently the CPM initiative, I think are two examples where there's been a very strong collaborative relationship between the networks, other agencies, and certainly with HCFA.

There have been some very important things that have occurred as a result of the core indicators projects. As you probably remember, there have been a number of arenas that HCFA decided that needed to be examined across the country. Among these, the adequacy of hemodialysis and peritoneal dialysis and anemia management probably have received the most attention.

The early reported years, in the '94-'95 sector, showed very dismal performance in many of those areas. We recognize that, but there have been documented and substantial improvements across all networks every single year. Even the facilities and the providers that have been performing at the highest levels have continued to show improvement.

We think that's partly because of the feedback

that the networks have been able to give directly to the providers. Being able to see where one is relative to our peers has been very, very important. Unlike other areas of medical practice, nephrologists are seeing where their responsibilities are playing out.

There are collaborative projects with some PROs that are already underway and I think there are more that are planned. Some of these certainly tie in with the PROs activities under their own scopes of work.

Some examples would include activities to decrease complication among diabetic patients, and certainly anything we can do to improve vascular access outcomes is going to be a very important point, since vascular access complications are responsible for the majority of hospital admissions among these dialysis patients.

The role of the state survey offices must be examined in more detail. Again, survey offices have to do with that quality assurance piece. They are the organizations that assure that facilities are properly inspected, that they do meet certain minimum standards.

There is an issue that we need to examine and that

is how one shares the data. The data that the survey offices collect and the networks collect are often from a common pool. We do share data.

But there is a concern that is very problematic in some areas and when data is collected, if it's collected for quality improvement initiatives, it's often provided in a very open-ended pattern. If one expects or anticipates that punitive action may be taken in result of that data delivery, there may be a different perspective. I think we just need to keep that in mind.

There have been a number of relationships with patients and facilities that the networks have long fostered and patient education, mechanisms of handling patient grievances, and things of that sort are regularly part of the networks table of activities.

We'll get into more detail of that, perhaps during the question period.

There is a question that's been posed to us about the accountability of the networks for facility outcomes. While that may sound like a very simple task to deal with, you have to consider that it may not be appropriate for the

networks to be held accountable for what happens in facilities themselves or even with specific patients.

The mandate originally, and which I think has been carried on, is so that the networks have to assure that the facilities have the right mechanisms in place. The networks have continually provided the support and the tools to examine various parameters, both for intermediate and long-term processes and outcome measures.

The networks, however, are responsible for very specific contractual obligations. These have to do with monitoring and measuring clinical indicators as determined by HCFA, maintaining the database of Medicare beneficiary information for quality improvement activities and other things decided by HCFA, and a number of others that are highlighted in this written paper.

Two points I want to make about funding of network activities, and again this is described in more detail, is that each network organization must provide a specific proposal to HCFA for funding. To the degree that those elements are mutually agreed upon, funding is obviously provided.

But as Dr. Diamond pointed out, with the extension of the Medicare secondary payer provisions to 30 months, a greater and greater proportion of people undergoing dialysis at any one time are non-Medicare beneficiaries. The time and the work that the networks operate under to continue to work with that data creates difficulties oftentimes, and I think that just needs to be considered in the whole discussion of any future funding.

The bullet points that I want to leave with you have to do with very simple things, I believe. One is that we're hoping, and I think anticipating properly, that the MedPAC will continue to support the networks in our quality improvement initiatives.

Secondly, the role of the networks in providing education and information both to patients, providers, and other agencies is critical and, according to Dr. Diamond's points, in terms of maintaining the infrastructure for data, it's a critical issue. There has to be improved interaction between networks and other organizations, especially PROs and even managed care organizations.

Lastly, we're asking that you recognize and

encourage implementation of a quality oversight system that recognizes and puts power into those two arms, one being the role of quality improvement and secondly, the external pattern of quality assurance. Those two must work in concert, and I do not feel that they can be within the same organization. We have mechanisms in place to deal with those.

I'll stop now and I appreciate your time.

DR. WILENSKY: Thank you. Mr. Nix?

MR. NIX: I'm Wayne Nix and I'm from Michigan. I am chairman of the Patient and Family Council of the National Kidney Foundation. I've been a kidney patient for 26 years. I was on hemodialysis for 17 years and while on hemodialysis worked as a teacher and football coach and then received a transplant in 1991.

I appreciate the opportunity to provide comments to the commission regarding the role of Medicare and ESRD quality measurement improvement and assurance efforts. I speak on behalf of the 10,000 members of the Patient Family Council who really represent a cross-section of the patients from across this nation, and also the 30,000 lay and

professional volunteers of the National Kidney Foundation who come from every part of the country and every walk of life.

Let me begin by acknowledging the fact that we have made some positive strides. We've just listened to the fact that there are problems, and yes there are. But we have made some positive strides in the care of ESRD consumers in the United States throughout the '90s.

We've seen the standardized mortality rate drop from about 25 percent. We've seen the anemia control improve and we've seen albumin levels rise.

This has been a result of the implementation, I believe, of the HCFA core indicator and also the National Kidney Foundation dialysis outcomes quality initiative guidelines.

As a former member of a consumer committee and medical review committee of Network 11, an opportunity open to only a handful of patients, and whose effectiveness depends upon the assertiveness of that individual and the circumstances during which they happen to serve, I'd like to address the efforts of the network as they pertain to

enhancing patient participation and strengthening the "hand" of the consumer.

The networks involvement, from a patient perspective, varies from region to region and usually involve any one of a combination of the following interventions to empower the patients. In some cases it may be a new patient packet of information that's provided to new patients. In some cases, it's a newsletter. It may be educational seminars. It could be a consumer advisory committee, a patient services coordinator who handles complaints and information, a grievance procedure, and efforts in the area of rehabilitation.

There's a need for all the networks to be providing each of the previously mentioned areas of support to patients across the country. It should be uniform and it should be the same that's being provided, as well as a more robust effort in the area of education since information is the best way to empower patients.

Though the networks and HCFA have made some attempts of the education of patients, much still remains to be done. Education is a process not a one-time affair. So

though the packets may be out there or they may be an educational seminar done once a year or something like that, it needs to be an ongoing process. It cannot be a one-time shot. Messages must be repeated for maximum effectiveness for patients. And patients must have access to educational opportunities when they're ready to digest the information, not when the provider or the network or whoever is ready to give it, but when the patient is ready to receive it.

Patients come to education at different times. And though a provider or a network or HCFA or whoever may be interested in doing some education, for that particular patient it may not be the appropriate time and they may not be ready for it because of denial, anger, whatever may be going on at that point.

So the information, if it's worthwhile, needs to be repeated, needs to be available, and needs to be there on a regular basis.

The must ensure that the patients receive adequate information in a consistent, timely, and unbiased manner, that everybody learns about all the modalities, that everybody learns about all the different things that need to

be presented in an unbiased manner.

Moreover, since patients health status may change over time, a continuum of education opportunities should be made available. Education should be individualized, based upon assessment of a patient's information base and knowledge gaps and in an evaluation of patients' understanding.

So really they should be pre-tested and they should be post-tested. And we should be continuing to educate people on a continuum and not doing it in a sporadic manner.

New materials need not be developed for this purpose. There's a wealth of educational materials and learning opportunities which are regularly available. Organizations like the American Association of Kidney patients, the National Kidney Foundation stand ready to provide collaborative help in this area.

I think in your packet of information you've got an example of the Family Focus newspaper, which happened to be the DOQI publication of this, which goes out to patients. It went out to close to 300,000 patients explaining the DOQI

guidelines and how they pertain to patients.

There's a need for collaborative efforts on the part of getting information out to people, and there's a need for the network and HCFA to be involved in that process.

Unlike some people may think, we're not psychotic, neurotic, sick people near death. We are rational beings that want to stay alive, are looking for information that will help to improve our quality of life.

For at least 85 percent of the dialysis patients, there's a wonderful opportunity to educate them while they are in treatment on hemodialysis for more than nine to 12 hours a week. HCFA and the networks should be overseeing that providers offer a minimum of at least 20 minutes of education weekly. One method could be over closed circuit television, another could be to provide a few laptop computers with CD or Internet capability. And they could be passed around among patients during the week for educational purposes and referral to programs also that exist, like People Like Us Life, and the RISE rehabilitation program of the National Kidney Foundation when they're offered in the

provider's area.

My final comments are going to be directed at the potential usefulness of HCFA's facility specific --

DR. WILENSKY: Can you try to summarize quickly the final comments?

MR. NIX: Okay. The consumer specific consumer information reports, there are about 60 dialysis units or centers in the Detroit metro area serving about 6,000 patients. Anyone of these patients is within a reasonable distance by bus, car or van of at least 15 of these facilities. Most patients do not know this type of choice exists. And even if they did, they'd have no way to present it to make an intelligent choice of providers or change if they're unhappy.

There needs to be a facility specific directory made available to patients to inform them of the choices in their area. Some of the topics that should be included, but not inclusive, would be types of modalities offered, if there's ongoing education provided, the transplantation rate, is an exercise program in place? Is a physician on site and available during dialysis? What is the standard

dialysis mortality rate and hospitalization rate in comparison with other facilities in the region? Do they offer transient dialysis? Implementing their unit to DOQI guidelines, and is adequate patient/staff ratio appropriate?

I'd like to close by saying that educated patients are empowered consumers and services of this and empowerment breaks down the fear and ignorance that need to non-compliance which results in more morbidity and higher cost to the health care system.

Thank you.

DR. WILENSKY: Thank you. Dr. Newmann, I see that in our listing we swapped credentials with Dr. Diamond. Our apologies.

MR. NEWMANN: Thank you. Do I have my 10 minutes?

DR. WILENSKY: You have 10 minutes. My concern is really, I think frankly that you will gain and we will gain by making sure we have the time for the commissioners to ask questions.

MR. NEWMANN: You have my biographical statement. I'm glad to be invited. I just began my 29th year as a ESRD consumer, having experienced all the dialysis modalities,

over 18 years on dialysis, 16 of which were with home hemodialysis plus various periods of peritoneal dialysis and in-center hemodialysis.

A cadaver transplant in '87 lasted only a few years and I've been enjoying a live donation of my daughter's kidney since Thanksgiving 1993. And to clear up some confusion, it is not necessary for me to sit when I urinate.

I have spent nearly 25 years as a patient, leader, activist and advocate. Kidney failure provided, for me, the opportunity to change professional interests from a developmental economist to a health policy analysis and research on dialysis and transplantation.

I'm familiar with some of your challenges. From 1994 through '96 I assembled and chaired the expert panel which made recommendations to ProPAC to compile rate changes due to scientific and technological advances.

Let me address the effectiveness of Medicare's efforts to enhance patient participation and strengthen the "hand of the consumer." Nancy Ray specifically asked that I look at this.

As Dr. Lewers knows too well, such efforts were seldom known by renal professionals or patients as objectives of the ESRD program. In the limited time available, let me illustrate a few of Medicare's activities which can be interpreted to include such patient consumer objectives.

One very good example, since 1980 one or more patients have been invited by HCFA, NIH, or HHS Secretary to join renal professionals on task forces, workshops, and other groups to develop recommendations or to provide commentary for topics ranging from patient rehabilitation, conditions of coverage for dialysis facilities, ESRD network scope of work, and more recently the working groups of public release of consumer information and state surveyors reports.

I often felt like a token patient representative among many doctors plus some nurses and social workers, dieticians and administrators. Nevertheless, I do feel we have been heard and our views taken seriously, for which I and other patients are very grateful.

I do have a suggestion. Since the Medicare ESRD

program is particularly for patients, why not spread the net more widely? Following HRSA's example, through its contract with the organ procurement and transplant network, invite more patients and family members to participate in these efforts.

Secondly, a generally recognized disappointment. Though required of each dialysis facility, a long-term patient plan for each ESRD Medicare beneficiary and an annual review are seldom effective or taken seriously. We seldom hear or read about nephrologists and renal team members inviting patients to work with them to discuss, develop, and carefully review a long-term plan.

We do hear and read that it should happen. We're much more familiar with the patient complaints about seldom seeing their nephrologist, not knowing what their long-term plan is, but remember signing something last year.

Of course, there are some notable exceptions when nephrologists, renal team staff and facilities take these very seriously, using them as effective tools for monitoring progress and improving outcomes. I don't know of any HCFA efforts to evaluate the compliance with and effectiveness of

these required plans.

Two suggestions: such an evaluation of the long-term plan, including recommendations for improvement, may be very useful. Second, with patients and renal team members, develop a short pamphlet or brochure similar to the Know Your Numbers brochure describing the importance, processes, and uses of long-term care plans and periodic reviews.

A third example: a useful addition, HCFA's brochure Know Your Numbers. This pamphlet, developed with suggestions from many different renal community representatives, including patients, serves as an educational tool enabling staff to explain the importance of adequate dialysis and also patients to ask appropriate questions and keep track of their monthly values.

The American Association of Kidney Patients in 1993, and soon after the Renal Physicians Association, produced and distributed similar brochures, though they were not as widely distributed as the Know Your Numbers.

Many of us realize the same important messages need repeating, not just to renal professionals but to patients. I don't know of an objective evaluation of the

effectiveness of this effort. Therefore, I suggest, given the wide distribution of Know Your Numbers brochure to nearly all dialysis patients, an evaluation may illuminate new insights revealing in which situations this brochure was used effectively. However, I don't know if too much time has lapsed for this to be accomplished.

Let me address my views on the effectiveness of the ESRD networks' efforts to enhance patient participation and strengthen the hand of consumers. The networks, with their data collection, have contributed a great deal to understanding and encouraging improved care and outcomes through the core indicators project, as has been mentioned. The networks are also required to provide patient services, grievance procedures, and have often developed a variety of educational programs, as Wayne suggested.

The 1998 ESRD directory, published by the Forum of ESRD Networks, includes 13 of the 18 networks list names of patient advisory committee chairs, although 28 percent or five networks list no one and those five networks cover 17 states. 12 of the 18 networks list a staff person responsible for patient services. However, 33 percent or

six of them list no one. And those six cover 21 states.

And finally, unfortunately, four networks, 22 percent of all the networks, listed neither position. And those four networks cover 16 states.

While the majority of networks do have personnel and patients assigned, I find the numbers which do not quite disturbing. A few networks place considerable emphasis on these positions. My impression, most do not. Network board of director and medical advisory board decisions seldom direct adequate use of most funds and personnel for these patient purposes.

I might add that network funding could very usefully be increased, specifically targeting increased patient participation.

I do know some networks have often helped patients with their grievances while others have done little. Patients are very often reluctant to reveal their names when expressing a grievance, fearing a threat of indirect retribution from those their very lives depend on for dialysis.

Strong patient activities committees are rare.

Some networks, with the best intentions, have earmarked funds for travel and support at PAC meetings, often only to find poor attendance because many dialysis facilities have not appointed PAC representatives. The representatives choose not to participate. Others are temporarily sick.

Occasionally, when there is strong physician or medical team support or encouragement, as well as strong network leadership interest in creating and maintaining effective PACs, they seem to succeed in developing educational programs, network policy suggestions, and so forth.

Let me talk about educational efforts supported by the networks and HCFA. I've had the pleasure of speaking to patient and family members in many states over many years, often at the invitation of networks, particularly those in Florida, Alabama, Mississippi, Tennessee, Indiana, Kentucky, Ohio, and Illinois. Wayne has done the same.

The programs are well designed, comprehensive, and normally provide a free lunch, which is a prerequisite to increase attendance among dialysis patients. However, attendance varies markedly, from 30 to 50, which is

disappointing, to 100 to 250, considered a success even though half of those attending are usually family members. Patient evaluations are normally quite positive, yet these programs reach so few patients, normally those who are participants in their care, of course there are always small numbers of new patients and pre-ESRD patients.

Some excellent newsletters and brochures have been produced. Some, but not all, networks compile and send information educational packets to new patients, as Wayne suggested. I have a suggestion, like Wayne's. Develop a policy enabling networks to receive the names and address of patients whose 2727 forms have been submitted by nephrologist and facility administrators, thereby enabling networks to send the new patient packages to patients while these patients are still new and haven't struggled through additional months of fear and uncertainty and develop inappropriate habits.

My time is running out. One other suggestion I have is that Medicare and the networks can play a critical role by supporting and funding efforts to distributer the many materials that have already been developed to patients,

and include an evaluation of the materials' impact. This is already planned. As I understand, HCFA will be requiring the networks to distribute to new patients the AAKP patient plan, describing various periods of patient experience with ESRD. That will begin in the mid-2000.

I also encourage such brochures as what Wayne suggested, the four dealing with NKF DOQI guidelines recommendations, as well as a whole series of publications by the Life Options Rehabilitation Advisory Council, which some networks already do.

Let me spend the last minute or two on the potential influence, the usefulness, of HCFA's facility specific consumer information reports. I think this is extraordinary, particularly with the principles of continuous quality improvement which Lou and Derrick have been suggesting are applied.

I do hope patients and families receive for the first time since the Medicare program began 26 years ago for dialysis patients, facilities descriptions and possibly risk adjusted mortality information, along with clinical measures such as adequacy of dialysis and hematocrit levels.

HCFA is making every effort to give renal community members the opportunity to suggest what should be released and how, so it is useful, reliable, and understandable. I have a number of expectations for the use of this information. A growing minority of new and established patients will look at it and may use it as one element in making decisions to stay at their present units, change units, or help new patients decide where to begin.

Most patients who use this facility specific information may realize their unit's results are pretty much like that of most others. Some might find their unit is outstanding, ahead of the pack. Others may find their unit is performing in some areas rather poorly. For those patients already concerned about the quality of care the unit generally provides, this information will be helpful. For patients who are generally satisfied with the care they are receiving individually, the information may be reassuring or it may stimulate discussion.

The most exciting and constructive potential use may be by the physicians, staff, administrators and corporate managers. They will see how their facility is

doing compared with the nearby CRT, CMF or LMNOP. The transplant community showed great interest in the release of center-specific results, and is using it to assist poor performers improve.

The networks have done this indirectly through the impact of and interest in the core indicators projects annual reports, even though single centers have not been singled out.

Networks have had and normally keep confidential the center-specific results produced by the USRDS. Now with some data available to the public, I expect an increased interest and pressure among all facilities to improve.

I have two final suggestions.

DR. WILENSKY: Please try to summarize.

MR. NEWMANN: This is it. HCFA and the networks develop programs and protocols requiring the renal professionals and administrators at better performing facilities to provide suggestions and technical assistance to their colleagues at the poorer performing facilities.

And finally, HCFA has considerable billing data by nephrologists and their patients, along with facility

outcome measures. It may now be possible to begin tracking nephrologist patient outcomes to increased accountability in the ESRD program while improving program performance. The large corporations collect and analyze this and may be interesting in helping HCFA and the networks.

You can be sure patients would like some objective rating of physicians to help them make choices or changes. Thank you.

DR. WAKEFIELD: Two questions, probably for Louis or Derrick. First of all, it seems to me that -- let me preface this by saying this is not my area of expertise that we're discussing here this afternoon. Having said that, it seems to me that any meaningful discussion of improving quality of ESRD treatment should probably include pre-ESRD quality aspects.

So I guess my question to you is, from your perspective, does the focus on pre-ESRD, that is access to early treatment and intervention in order to decrease ESRD incidents, does that focus need to be significantly strengthened? And if so, how?

The second question I have for you is do the ESRD

networks include any active participation by the Federal Indian Health Service? The reason I'm asking that question is because of the high incidence of diabetes and ESRD in that population.

DR. DIAMOND: A quick answer to the first. Yes, looking at the pre-end-stage renal disease is important. I know the RPA and ASN are currently conducting various efforts to evaluate that patient population and get an understanding of what their disease burden is, from what the referral patterns, early referral might do. And there's some preliminary evidence to say that early referral might, in fact, be beneficial to that patient population.

I've got to tell you, personally, I'm focused on the end-stage renal disease program right now, in terms of what I spoke with you about today. Because we've got to start somewhere and there's much work to be done in that particular area.

I can't answer the question about the Indian Health Service. It may be that the networks can answer.

DR. LATOS: There is nothing specific for the Indian Health Services programs. They would be represented

within the regions and the networks that serve them. It's an important point to focus on, though, and I think we can get more specific about that.

There's no doubt that the incidence of Type I diabetes, for example, in that population is extraordinarily high. I think the networks that serve those patients probably are making that a priority anyway.

Back to your first question, however, I can't agree with you more, that there needs to be some intensive focus on what we need to be doing in the pre-dialysis setting. There's a lot of data right now that shows that some interventions are very meaningful in terms of forestalling, preventing the development of renal disease. But more importantly, for that large number of patients who are going to progressively lose their kidney function, we can do things to get them better prepared for dialysis.

Preemptive renal transplantation is one example. You can't do that when you've seen the patient for the first time with a creatinine of 10. So early referral was only one piece.

We recognize there has to be a lot more education

of all practitioner groups, including nephrologists, about what it is that we need to do in that pre-dialysis setting that really counts. Blood pressure control being one. Blood pressure control being two. Blood pressure control being three, and on and on. So I support that completely.

DR. WILENSKY: Any other questions?

DR. ROWE: On the Indian Health Service, I think the incidence or the prevalence of diabetes is very variable. It's very high in the Pima Indians and in certain subsets, but in other populations of Native Americans it's not extraordinary.

DR. WAKEFIELD: It's extremely high where I come from, North Dakota, in the Sioux population. As a matter of fact, I think the IHS would say the highest incidence of any subpopulation within the U.S. is in the Native American population, but I'm sure there are those variables.

MR. NEWMANN: I do know that over the years the Pima Indians have been well represented in Arizona in these various work groups, invited by HCFA and the networks. Their nephrologists are well tuned in to this system.

DR. DIAMOND: I just want to make one point, if I

could. I think it's going to be very helpful going forward for us to make a distinction between the knowledge gap, in terms of understanding better what we should do with a given patient population, versus bridging the implementation of the knowledge that we actually know.

The point I made earlier is I think we know a lot about the gap of performance in the end-stage renal disease population. I believe that at the moment the question for pre-ESRD is a research question in large part. And that's why I make that distinction.

DR. LEWERS: Just one question while we have Lou and Rick here. HCFA is adopting or proposing that the Native arterial vena fistula is a measurement of quality outcome. I have a bias on some of that, and I'm just curious whether either one of you had a comment?

And then you all have given us a lot of things you think we could do or should do. I think I would know your answers, but I wonder -- because we're going to be discussing this in our next session -- is where do you see MedPAC fitting in this, if you had one thing, if each of you had one thing we could do, what would you recommend that

that be?

DR. DIAMOND: On the fistula issue, Ted, the AV fistula question, as I understand it at least, is an attempt to put in place a quality measurement and improvement program. There are a lot of open questions. There are a lot of questions about how we define the measures, et cetera. I don't believe that what HCFA is attempting to do is establish a standard, but rather with the community establish a measurement system.

So at one level I have less concerns about that. I think we're going to have some difficulty getting that done because there's some complicated issues, which I think you allude to.

I would land on, I think, and I'm obviously in a minor way conflicted here because I do serve on the National Patient Safety Foundation. Of the two initiatives that I listed, I listed seven, the patient participation issue is critical for me. And putting in place, and I think MedPAC can do a lot of work in that area and make a lot of recommendations, and the adverse drug event issue. Establishing a reporting system within the umbrella of a

quality improvement program would be, I think, critically important.

Adverse drug events is the lower hanging fruit, in my judgment, in the quality improvement scenarios that we are faced with.

DR. WILENSKY: Do the rest of you want to respond to that?

DR. LATOS: I would extend that to adverse events, however, not just drugs. Those events can be a number of things occurring in the dialysis arena. I agree with Lou, I think that the patient focused issues are key, whatever we need to do there.

DR. ROWE: Do you think they're more important than increasing the payment?

DR. WILENSKY: We've already recommended that.

DR. ROWE: I know, but I just, you know, I haven't heard. I would have thought that one thing everyone would agree on would be increasing payment.

DR. LATOS: Real quickly, and I'll turn this to John, I think the payment question is very important because there's no question that it is very difficult to care for

elderly debilitated patients that come to us very, very ill with staff ratios that may not be what we would like for them to be. The costs to provide that care go up every year. The dollars coming in from all sources continue to be flat, if not decreasing.

So if we're going to deliver high quality care, somewhere we have to figure out how much it's going to cost to do that. John, you can comment.

DR. DIAMOND: And quality costs money.

MR. NEWMANN: As some of you may know, the networks are financed through the composite rate. And so you can perhaps kill two birds with one stone by developing a proposal which would require additional patient, in my view, distribution of educational materials or patient participation in some fashion of the networks. And in your recommendation for increasing the rate, tie some of that recommendation to those issues.

MR. NIX: There's no question in my mind that the key to this is patient education and patient empowerment and patient involvement. It's got to be grass roots, where the patients are demanding change and demanding the right

treatment, they'll get it. I see this time and again, when we educate people and they get back and request things, they end up getting them.

So I think education is important. It's also a compliance issue. When people have fear and ignorance and don't understand what's going on, about the only thing they can do is refuse to do things or not want to -- you know, that's a way of expressing their control of life again.

So education is important. I can't emphasize how important that is, the key for patient survival.

DR. LONG: Coming back and following up on Mary's question about pre-ESRD situation and Dr. Diamond, your comment about research. Our materials indicate studies showing an average duration from initial referral to a nephrologist to the initiation of dialysis of three months. I don't know clinically what sense to make of that.

Should it be six months? Should it be three years? Should it be six years? Is that what we need research on? Or do we know what we ought to be seeing, in terms of understanding earlier on the kinds of indicators that ultimately would lead to dialysis or that would

indicate other interventions that would defer postpone the need for obviously the most expensive interventions of dialysis and/or transplantation?

And here then aren't we talking about education of a broad sector of the community that has nothing whatsoever to do with the nephrologist or the patient?

DR. DIAMOND: As far as I know, and I haven't done a lot of research on this, but I did attend a recent conference on a panel that AHCPR sponsored on referral, we do not know answers to, I believe, some fundamental questions. The question of what is the duration of appropriate referral prior to institution of dialysis.

There is some preliminary evidence that a longer duration is better than the shorter duration. But what we haven't landed on are what are the interventions that, in fact, drive that finding. So I don't think we know the answer to that. And that's why I put that particular question, very important, into the new knowledge research arena, in my mind at least.

I may just be not knowing all of the issues. I'm just not ready to recommend a set of policies based on the

evidence that is out there. I think it's a question that needs to be dealt with.

DR. LATOS: I was being a little cynical when I focused just on the blood pressure intervention in the pre-dialysis patients. They are obviously things far beyond even what a nephrologist does. Nephrologists who see patients prior to initiation of dialysis have a mechanism of funding. There's a fee-for-service billing, there's a referral pattern in a managed care organization.

But many of the important interventions that probably make a big difference have to do with areas of dietary nutritional interventions, social work interventions for purposes of planning and educating. Most of the social workers and dieticians that we work with live in dialysis units, and there is not a mechanism to fund those activities other than through the dialysis programs.

I don't know the answer to how we get there, but we don't know yet which interventions count the most. It's not just what the doctor does. That education piece that Wayne was talking about is very, very important, not just for patients but you were talking about the duration. Three

months to dialysis is hardly enough time to let an AV fistula mature, for example.

There is no way that we have enough nephrologists in this country to care for everyone who has kidney insufficiency. We have to develop new models of how we interact with primary care physicians, nurse clinicians, and others.

And once we get there, what's the role of the various components? What's the role of nephrologists at what point in time? That's a research question that's not been answered yet. A lot of work going into it.

DR. WILENSKY: Thank you very much. Nancy?

MS. RAY: In your mailing materials and the panelists were specifically brought in to talk to you about Medicare's role in dialysis quality assurance and improvement.

I'm seeking input now about our research strategy that we've proposed in our workplan and identifying important issues for analysis. If you can give some indication of issues that are more important to you than others, or whether you would like more of a general approach

or a specific approach.

We anticipate that the issues about ESRD quality assurance and improvement will form the basis of some sort of chapter in the June 2000 report. The first issue is quality assurance and specifically Medicare's conditions of coverage for dialysis providers. There's a number of issues that the commission could consider to address.

That includes their reliance on structural process measures and not on outcome measures, the fact that the conditions do not specifically set forth requirements for an adverse event reporting system as was discussed by the panelists. And thirdly, with respect to the training, the fact that dialysis technicians, which account for a majority of the staff in the facilities, that the conditions of coverage do not require any type of minimum training.

With respect to state survey agencies certification of dialysis providers, again there's a number of issues that the commission can choose to address and discuss. Some of these you've already heard from Helaine and the previous panel on the state survey issues.

The first issue is the general issue about the

priority of dialysis facilities, the fact that the frequency of inspection is not statutorily specified in the statute. And the variability of funding for surveys of dialysis facilities and the training involved in state survey personnel.

The second issue that the commission can choose to address is with respect to private accreditation. Again, right now, as we discussed earlier, Medicare has not enacted deemed status for renal accreditation organizations.

The third issue under the state survey umbrella that the commission can consider is HCFA's development of facility specific profiles. These were discussed in your background information, in your mailing materials.

I think there's a couple of issues that the commission can address. The first is the process by which these measures are being developed. HCFA has held a stakeholders council meeting back in June and is currently in the process right now of developing the measures. So we don't know yet what the measures will look like.

There have been concerns from some ESRD stakeholders, however, that there was not adequate

discussion of these measures.

With respect to quality improvement activities, overall the commission can address how well Medicare's quality improvement activities are in the ESRD arena. With respect to establishing and articulating national goals, as well as building partnerships with ESRD stakeholders.

On the more specific level, the commission can address quality measurement and improvement with respect to HCFA's ESRD clinical performance measure project. As was outlined in your mailing materials, the clinical performance measure project was merged with the ESRD core indicator project in March of 1999. Phase two of the project is ongoing right now. It started in February and it's going to be completed in March of 2000. It involves pilot testing the 16 clinical performance measures, using a similar methodology that was used in the ESRD core indicator project.

At issue, and this was something brought up by the panelists, specifically Dr. Diamond, are we addressing all relevant processes and outcomes? The clinical performance measures are based on the DOQI guidelines. So therefore,

what the clinical performance measures are addressing right now is adequacy of dialysis, anemia control, and vascular access.

The clinical performance measures, therefore, are focused on selected process and outcomes of dialysis care, not all of the care that ESRD patients receive. In addition to that, there's no functional status, quality of life, or satisfaction of care data being collected. Nor is there any information on patients' co-morbidities. Unlike the ESRD core indicator project, right now the clinical performance measures do not measure nutritional status.

With respect to the network activities, a number of issues for the commission to consider, what can be done to further the effectiveness of their efforts? We heard from the panelists about additional patient education to be provided by the networks and their role in supplying and empowering patients.

Another issue is the accountability of the networks. Should they be accountable for facilities in their region for continuing improvements in outcomes?

The third issue is should their focus be broadened

to look at all of the care that ESRD patients receive? So to address the co-morbidities that ESRD patients have.

And the fourth issue is again, the funding mechanism for the networks. With the extension of MSP to 30 months, and with the Medicare only patients, the mechanism right now to fund the networks is 50 cents from every composite rate dialysis session and whether or not there should be some modification of that.

A last issue to consider, as far as the quality improvement, is right now there is about 17,000 ESRD patients enrolled in managed care organizations, and whether or not there needs to be a specific project, project, to measure quality for those patients similar to the sample that was used in the core indicator project and that's now used in the clinical performance measure project. Should an annual program be developed to measure the quality of care of ESRD patients in managed care?

The last issue that I included in your workplan is an issue about pre-ESRD care. Some say that early referral to a renal team may delay progression of ESRD, reduce complications when patients become ESRD, and may ultimately

increase survival.

There's clearly a lot to learn about the pre-ESRD area. In fact, NIH just held a conference on patients with chronic renal insufficiency to gather information about a potential prospective observational study, cohort study, that they are thinking of conducting to find out more about what the outcomes and what effective care does among chronic renal insufficiency patients.

I put this issue in your mailing materials to provoke your interest about whether or not Medicare should perhaps consider setting up a demonstration project in this area in which Medicare would actively identify beneficiaries with chronic renal insufficiency and perhaps refer them to a renal management team.

The third part of the quality improvement and quality assurance chapter that I see is on consumer empowerment efforts, how effective they have been, specifically with respect to HCFA's facility level consumer information reports. Again, these are in the developmental process right now and we do not have any draft measures yet.

But this will be information on a facility level

that will be provided to patients. This is something that ESRD patients in the past have never had and will enable them to make better choices about where they get their care.

In the past, HCFA's primary tool in providing information to patients has been with its Know Your Number brochure, and this is in the process of being modified. There are plans for an ESRD website some time next year.

I think at issue with the facility level consumer information reports that the commission may want to consider is that -- and again, this was mentioned by the panelists. But again, there is no national level data on aspects of care that are important to dialysis patients.

There have been some studies done by private sector groups, notably Johns Hopkins researchers in their AHCPR funded report have conducted several focus groups of hemodialysis patients and peritoneal dialysis patients, looking into what aspects of care are important to them. And have found notable differences between hemodialysis and peritoneal dialysis patients.

The development of the facility level consumer information reports, as well as any other consumer

empowerment effort being conducted by HCFA, is being done in the absence of national level information and whether or not this gap of information could provide additional knowledge in helping to better tailor information targeted to the patient.

I would like the commission to give staff specific guidance on areas of interest.

DR. MYERS: On the last slide. It's not just the information, it's the ease of comparability of the information, as I think Mr. Nix made in his last several points. It's being able, especially in the major metropolitan area, to see across a facility so that you can easily look at your choices and how your choices compare in making a rational judgment based upon that information.

So I would daresay it's not just having a piece of paper showing what XYZ facility is like, but being able to look across and being able to make decisions.

MR. MacBAIN: I think I heard a couple things. One was patient involvement in a lot of ways, and that's patient education and the management of his own disease, as well as what Woody's talking about in terms of alternatives

that are available. And involvement a step beyond that, as you're discussing in whether the materials themselves or the policy decisions themselves really meet a patient need.

But the other, I think in particularly Dr. Diamond stressed, was the potential impact for decision support tools in preventing adverse events. He was using drug interactions, but I think as Dr. Newmann or Dr. Latos said, it goes beyond that. And without getting too specific, that may be something we want to look at, is incorporating the development and use of decision support tools.

DR. KEMPER: I have a number of comments here that I can give you separately, but just let me mention a couple questions. One is how is this different from the quality assurance discussion we heard earlier? A lot of the issues are the same. So maybe part of the response is ditto, just to step back and take the more general rather than the very focused questions.

I guess at a number of places in the workplan you talk about assessing something in order to make a recommendation. For example, you talk about assessing conditions of participation to conclude whether or not HCFA

should establish staffing criteria. I wasn't sure exactly what an assessment would be and how we would actually come to those recommendations because it doesn't strike me that it's easy to assess some of these things. And what would be our contribution?

MS. RAY: Right, I think specifically the conditions of coverage, there's a couple of ways to approach that. The first thing is we can look to see what the states are doing with respect to licensing of dialysis facilities, if they have more rigorous, more additional requirements than the Feds have. I think with respect to dialysis technicians, we could definitely do that. There are several states that are already taking the lead in requiring minimum training for dialysis technicians.

Those are the two things that came to my mind initially, on how we would address that.

DR. KEMPER: We might not conclude that that necessarily is a good idea, just because it's being adopted in the states.

I guess my last thing is really a question.

DR. WILENSKY: We definitely don't want to presume

that that's necessarily a good idea just because it's been adopted.

DR. KEMPER: That's what I meant. The last thing I had was really a question and maybe you can help me, whether we ought to view the quality information and improvement efforts here as a failure or as a model to be copied by the rest of Medicare? In some ways, I look at this compared to the other parts of Medicare. I see where there really are clinical measures. There is a mechanism to collect the clinical data.

It's being monitored and apparently, I understood from the testimony, that there's been improvement and working with providers to actually improve it. It almost seems like it's a success story relative to some other parts, rather than failure.

So I didn't know if you could comment on that.

MS. RAY: Right. I would agree with you 100 percent. I think ESRD -- you can always, of course, improve something. That's very easy to pick on something. But I think ESRD is a model for other areas in Medicare to try to emulate in a way. I think with respect to the relationships

that the networks have with dialysis providers, as far as quality improvement.

I think with the development by private sector organizations, for example the DOQI guidelines, and the ongoing project right now which is privately sponsored by Amgen that's looking into best practices. I think that in a way the ESRD sector is ahead of other providers, as far as measuring quality and improving itself, and actually shifting the curve to the right.

I also think that with the development of the information system that was outlined in the workplan with SIMS and that eventually when the facilities will be hooked up to the networks which will be hooked up with HCFA, there will be a lot of potential for even more quality improvement.

So I agree with you, I think, a little.

DR. KEMPER: So I would think taking it to the next step, to the facility specific reporting, that that's a very controversial thing that would merit some discussion.

DR. LEWERS: I was going to point out something that Nancy Ray has already pointed out. I think there is a

story here that perhaps could benefit other segments of the HCFA community. But I think some of the things that you've talked about, and you talk about in your paper, are major research projects that I don't think are the purview of the organization.

If we could tie together some of the state programs with the adequacy of dialysis, some sort of real true quality measurement, that would be a major step forward. Maryland had the first and probably one of the best kidney disease programs in the country. What you heard this morning from Oregon, I don't think, would have happened in Maryland.

I remember my units used to get inspected a couple of times a year. And so if I'm getting twice a year and some of them are getting it every five years or more, then we've got some that aren't getting it at all. So if there's some way you could look at that, that would be fine.

But I think we have to be careful not to bite off more than we can accomplish. It is a huge problem but there has been success, and I think we ought to take the opportunity to evaluate that.

MR. SHEA: Pretty much on the same point as Ted. It would be useful to get an evaluation of whether or not we can learn anything by comparing state A to state B, in terms of the quality assurance end, and to see if there's any data that would be the basis then for making more general recommendations.

DR. WILENSKY: A couple of comments I wanted to raise. I think consistent with what Peter said about going back to the earlier discussion that we had, and the tension between quality assurance and quality improvement comes up there a couple of places when you talk about the quality assurance activities, and particularly about some of the staffing input requirements. It seems to me that the discussion we had about the tension and focusing on process measures, like staffing as opposed to outcome measures, and the tension between improvement and assurance is relevant here and you ought to make use of the comments and discussion that we had there.

For my own opinion, I think that the notion of looking at whether Medicare ought to be proactive in identifying pre-ESRD patients and talking about setting up

programs for them, is somewhat beyond the scope of what we are being asked to look at. I think the issue of having a discussion of that in the quality chapter, that this is a whole other avenue that Medicare could pursue if it so chose, is fine. But I think it really takes what is already the largest single disease program in the country, and yet is a substantial potential opening of boundaries that goes -- at least what I would be comfortable feeling -- our mandate and charter.

But I don't think there's anything wrong with saying this is an issue that Congress, if it so chose, could wish to consider, given that it has already set up a program that makes these individuals ultimately Medicare's responsibility. But I would feel uneasy about getting into an area that we might be in a position of recommendation such a strategy.

DR. KEMPER: Gail, the only reaction I would have to that is -- and I understand wariness about creating a new benefit. But at the same time, if there were evidence of prevention, most of the costs are going to be borne by Medicare in the end anyway. The review of the literature

seemed to make sense to me on that score, if there were --

DR. WILENSKY: But it's strictly within the context of a review of the literature in terms of what we know about this issue, as opposed to going to making specific recommendations. Obviously, HCFA can consider, or the Congress could consider if it so chose, mandating a demonstration basis to see whether it thought it was really cost effective.

As you know as well as anyone, our ability to sufficiently target people who will actually end up in a more expensive venue has historically been poor, to put it kindly.

DR. NEWHOUSE: That was the point -- on that specific point, how cost effective it is to identify people is going to identify on the prevalence of the disease in the population you're looking at. I just am skeptical that the literature will go that far, but maybe it will.

MS. RAY: There aren't firm estimates right now and it varies depending upon who you talk to, how many people are in that chronic renal insufficiency set.

DR. NEWHOUSE: No, but it's not just how many

people there are nationally, if you go to North Dakota versus if you go to Manhattan how many people are there? Or even in different parts of Manhattan? Because the cost effectiveness will vary.

DR. WILENSKY: Anyway, if we want to discuss this as an issue, it strikes me more that this could be raised as something for some further thought, as opposed to us trying to get too far into it again, is my opinion.

DR. WAKEFIELD: I was just going to second your point. I guess I'd say my guess is there might be more people in North Dakota affected by this problem than in Manhattan.

DR. NEWHOUSE: Depends which part of Manhattan.

DR. WAKEFIELD: Which part of North Dakota, too.

DR. ROWE: There won't be more people in North Dakota --

DR. WAKEFIELD: A proportion.

Gail, I think the way you're pitching this is, from my perspective, a good approach. And that is to raise the issues in a discussion, in terms of pre-ESRD care, I think it certainly merits that kind of a discussion. But as

far as trying to move it further into recommendations, I'm with you on that. I think it's a little bit premature, but I'd sure like to see a little bit of discussion in the report on that.

DR. LAVE: This is on that point. Nancy, and the other people around, I believe at one point HCFA was being pushed to do some pre-nutritional interventions to try to delay the onset of ESRD. And HCFA, for a while, was really being --

DR. NEWHOUSE: We discussed that.

DR. LAVE: So that would really fall in this bailiwick. I don't think it did anything. Did it do anything, Joe?

DR. WILENSKY: What we talked about was the nutritional as part of the increased composite rate.

DR. LAVE: No, this was pre-ESRD.

DR. WILENSKY: Thank you. Stephanie?

MS. MAXWELL: I'm going to try to capture some of the pre-BBA and post-BBA landscape about therapy services generally and then walk through the BBA provisions regarding outpatient therapy services and our models regarding the

therapy caps.

Please note that there's an appendix included in your materials which is intended to furnish some more detailed information about outpatient therapy coverage rules, payment rules, and about the main providers for these services. On the ambulatory side, that includes mainly the hospital outpatient departments, rehabilitation agencies, CORFs, and then it also includes SNFs for the SNF Part B patients.

Note that the SNFs and SNF patients are affected by these rules mainly because Medicare pays for therapy under these rules for patients who remain in a SNF following their Part A stay or for patients that weren't qualified for a Part A stay to begin with. In other words, if they didn't have mainly a hospital stay, prior to that, up to three days or at a minimum of three days.

The BBA enacted substantial changes in Medicare's post-acute payment policies and therapy, whether furnished on an inpatient or an outpatient basis of course is integral to much of post-acute care.

This slide represents the post-BBA landscape so

far. In other words, it lists the post-acute payment changes that have begun already. In all these venues, therapy services took a hit and the payment moved away from cost-based payments. Payments are determined prospectively under the SNF PPS, they're subject to limits on the home health IPS, and they're based on the physician fee schedule and subject to the $1,500 caps in the case of outpatient therapy.

Certainly not all patients and all providers are affected by each of these changes, but of course some patients plan of care do take them through more than one of these settings. And of course, many hospital systems have multiple lines of post-acute business. And further, some contract therapy companies furnish services in multiple settings, as well.

In many respects, the post-acute policy landscape prior to the passage of the BBA was one of concern among policymakers about the overall growth in spending and the appropriate use of post-acute services. Concerns appeared greatest regarding the growth in SNF and home health use. Aggregate Medicare expenditures for those services certainly

dwarf those for outpatient therapy services.

For example, in 1996, SNF patient services accounted for about $12 billion in Medicare payments, and home health services accounted for about $17 billion while outpatient therapy services accounted for about $1.5 billion.

In terms of growth rates in the '90s, aggregate payments to SNFs rose about 33 percent annually. Most of that growth was due to rising therapy payments and other ancillary services, including drugs and labs, rather than for the room and board payments. Also, the number of SNF admissions rose only 14 percent during that period, but the payments rose 33 percent.

In addition, several studies at the time by the GAO, by the OIG, and by other researchers were documenting the increase of therapy services specifically to both Part A and Part B SNF patients. Some of these studies were questioning whether all of that growth was appropriate.

For Medicare coverage purposes, inappropriate or unnecessary therapy includes skilled therapy when unskilled or maintenance therapy is considered more appropriate, or

when therapy is considered overly extensive or frequent in combination with unrealistic goals regarding patient function.

Even after the BBA, some concerns remain about the appropriate use of therapy in SNFs. For example, this year the OIG surveyed a random sample of 24 SNFs totaling about 218 Medicare SNF patients. They looked at the medical records and the bills for those patients and found that about 13 percent of Part A and Part B therapy was considered medically unnecessary. By the different facilities, that number ranged from 0 percent to over half.

An additional 4 percent of the therapy was billed for but not even documented at all in the patient's records.

Those studies focused on the SNF therapy services and didn't include therapy in the ambulatory settings. Meanwhile, aggregate payments for outpatient therapy in the more ambulatory settings, the hospital outpatient departments, the rehabilitation agencies, and the CORFs, also rose fairly rapidly in the 1990s. Between '90 and '96, expenditures for therapy payments in those settings rose about 18 percent a year.

So those were the trends that were in place when the BBA was passed. Regarding the outpatient therapy services, the BBA changed both the coverage and the payment policies. Effective January of this year, of '99, Congress ended cost-based payment for the outpatient therapy services and required that payments be based on the fee scheduled used for physician services.

Of course, the most publicized provision was the establishment of coverage limits for these services, the $1,500 caps. Less interestingly, but quite importantly on a technical level, the BBA also required providers to start putting service codes on the bills. A service code wasn't necessary for payment in the past. Indeed, when we looked at the coding on the claims, we found that the information was quite spotty and generally not usable.

The Congress did indicate that future coverage for outpatient therapy services should be determined by some sort of patient classification system and not by dollar coverage limits. The BBA requires the Secretary to submit a report that develops some kind of recommendation for classification policy based on diagnosis and prior use of

inpatient/outpatient services by January of 2001.

Part of the reasons for requiring a coverage report three-and-a-half years after the BBA rather than sooner is because it will really help HCFA and other researchers to have those CPT codes on their claims.

About the coverage limits, the BBA imposed a $1,500 per-beneficiary cap on annual Medicare coverage for outpatient physical and speech therapy, and a separate $1,500 cap for outpatient occupational therapy. After 2001, the limits would be updated by the medical economic index and presumably, in future years, by the new coverage policy.

Both of the BBA provisions, the fee schedule reimbursement and the dollar based coverage limits, have been in effect for several years on the independent providers of therapy. Indeed, one of the goals of the provision was to level the playing field between the independents and the outpatient facility providers.

Note that therapy furnished in the hospital outpatient departments are exempt from these coverage limits. Also note that $1,500 represents the total coverage and that 20 percent of that is for the patient co-pay, and

the other 80 percent is for the program.

DR. ROWE: I want a clarification, particularly given some of the provisions currently being discussed on the Hill, and with respect to some of these.

The second paragraph here, Stephanie, this says $1,500 for combined physical therapy and speech therapy or for each?

MS. MAXWELL: Combined.

DR. ROWE: Is it $1,500 per beneficiary or per beneficiary per facility?

MS. MAXWELL: Thanks for asking; you're previewing the next paragraph. It's per beneficiary according to the BBA, and it's currently implemented per beneficiary per provider.

DR. LAVE: Could I ask a clarification? It looks as if the BBA improved coverage rather than limited coverage. And all the discussion would seem to imply that it made coverage more restrictive.

If I look at this it looks as if, in fact, the BBA improved coverage, in the sense that it went from $900 to $1,500. And yet all of the rhetoric would seem to imply

that it decreased the limits. So can you explain the difference between the two?

MS. MAXWELL: Yes, I can explain that. The $900 limits were the limits applicable the last couple of years, before the BBA, for just the independents. These outpatient providers, the agencies, the CORFs, the hospitals and now the SNFs, were not under any limits at all and their payments were cost-based.

DR. WILENSKY: So it was literally the question of the independents changed, it actually was more generous for the independents relative to what they had been, neutral for the outpatients since there are no limits, and more restrictive for the nursing home, more or less.

MS. MAXWELL: Yes, that's how it worked out. Not particularly given the original BBA implementation, but given the current implementation, absolutely.

DR. NEWHOUSE: Then, Judy, several of the independents were morphing into agencies.

DR. LAVE: So the rehab units and rehab hospitals that did outpatient care are now covered but weren't covered before?

MS. MAXWELL: The services were always covered by those providers.

DR. LAVE: No, I'm talking about the limit.

MS. MAXWELL: Except for the fact that -- they would be covered but if they're hospital outpatient departments. If it's a rehab hospital, they're not under the limits because of those being exempted.

DR. KEMPER: And the reimbursement rates changed, the payment rates changed.

MS. MAXWELL: Right. Those changed from being cost-based to the fee schedule.

DR. KEMPER: Which I assume was a reduction, most often a reduction?

MS. MAXWELL: A little less so for hospitals, given that they were already subject to savings reductions in the past. That's certainly fair for the agencies the CORFs.

As Joe had mentioned, part of the level the playing field issue and part of the loophole issue was to bring the outpatient providers into the caps and the fee schedule because, as he said, some of the independents

recertified themselves as agencies as they moved on to the physician fee schedule in the early '90s.

It seemed to be that the fee schedule and, I guess, kind of the administrative problems they felt with that was more of an issue than their caps. The independents had been under caps since the mid-1970s. But that morphing started to happen in the mid-'90s, early to mid '90s.

As you were mentioning, the issue about how it's implemented is a very important issue right now. It's because of the certain computer limitations of HCFA and its FIs that they're being implemented right now on a per beneficiary per provider basis. That means that patients are covered for up to $1,500 of each group at any given non-hospital provider.

A patient who's exhausted his or her coverage limit at one agency or one CORF can go to a second agency or CORF. Or of course, they could just go to the hospital, as well, for unlimited coverage.

A really important caveat to this interim implementation method affects the patients receiving these services in SNFs. Because of the BBA's consolidated billing

requirements affecting SNFs, these facilities can't restart their coverage limits for their patients by simply using a different therapy provider. All outpatient therapy furnished to a particular patient in a particular SNF counts toward their $1,500 coverage limit for that patient in that SNF.

Without the consolidated billing requirement, they could possibly furnish it as a salaried in-house therapist provider, they could have a contract provider for a separate round. The consolidated billing requirements don't allow that.

DR. ROWE: But they could spend a patient across the street to a facility that they own.

MS. MAXWELL: If they do that, they still have to count that to their $1,500.

DR. LAVE: That's for Part B as well?

MS. MAXWELL: Only for the Part B. The consolidated was part of the whole PPS legislation, but it certainly affects these patients under those Part B rules a little more differently than the more ambulatory oriented outpatient therapy patients.

Before turning to some of the beneficiary level information, I want to give you a sense of the breakdown of these services and patients by setting. As you can see, most of the patients and expenditures are in the more ambulatory settings. In other words, in the hospital OPDs, the agencies, and the CORFs.

Of these settings, though, a disproportionate amount of payments go to the agencies and the CORFs. As I mentioned a little bit before, part of that is due to the fact that in the '90s the hospital outpatient departments were subject, for all of their services, to reductions to their cost-based payments for savings purposes. The rehab agencies and the CORFs, however, were paid their full reported costs.

On another interesting note, though, in our prior research on the outpatient therapy patients in these ambulatory settings, patient diagnosis codes did not explain any of these difference in payments in these three ambulatory settings.

Overall, the payments in the three settings, the more ambulatory ones, totaled about $1 billion in '96. To

the SNF Part B patients, it totalled about $400 million. By the way, we'll have '98 data available in a couple of weeks.

The users column in this slide represent about 1.7 million therapy users in the ambulatory settings and about 300,000 users in the SNF Part B setting.

On average, Medicare spent about $875 per outpatient therapy patient in '96. Again, this does include the Medicare's payment amount plus the 20 percent co-pay. It also is an average of all of the three types of therapies.

As you can see on this slide though, breaking down the different types of therapy and the settings, you see that the average payments were definitely much less than the hospital outpatient setting but were relatively similar in the other settings.

Across the settings, we can see that most patients did have substantially lower payments than the cap on that. For example, the physical and speech payments per patient totalled less than $1,000 for three-quarters of the patients. The $1,500 amount is at about the 86th percentile point.

DR. ROWE: So this includes patients who didn't have the cap -- this includes people who were at hospitals, therefore they went beyond the $1,500?

MS. MAXWELL: The first slide did include the hospital users and all the other settings.

MR. MacBAIN: This is '96.

MS. MAXWELL: Right. So what we were looking at is just whether or not they reached -- where they reached the $1,500.

DR. WILENSKY: This was pre-cap, but they would have been, had they not been there in the next year.

MS. MAXWELL: Right. Now this slide shows the annual payments of the 14 percent of all the users that were over one or the other of the $1,500 amounts. As you can see, about half of these therapy users had up to about $2,700 of services, or in other words up to about $1,200 more than the $1,500 cap amount.

The top 5 percent of users, on the other hand, had over $8,500 in services or about $7,000 over the cap.

This summer and fall the Congress and HCFA have considered several short-term alternatives to the current

coverage limits. Some under consideration have included establishing a separate cap for speech, rather than a combined one for speech and physical therapy; establishing an overall cap at various levels for all three services; exempting patients with particular conditions or diagnoses that typically exceed the coverage limits; and also establishing facility level average limits rather than beneficiary specific limits.

We estimated the share of therapy users that would exceed several versions of these alternatives. The options that have been most under consideration are shown on the next three slides here. They're also shown on a single table in your book. I'll just run through these very quickly, focusing on the last bullet point within each scenario.

Assuming the current $1,500 caps, 14 percent would have exceeded that in 1996. If those two caps, between speech and therapy, were split and everything was still set at $1,500, about 13 percent would exceed.

If the two caps were set at about $2,000 then about 10 percent would exceed one or the other. If the caps

were set at $2,000 and the speech and physical therapy cap were split, then about 9 percent would exceed one or the other.

If a total combined cap was set, then about 4 to 7 percent would exceed a total cap, depending on where you put it. As of two days ago, the Senate Finance Committee is leaning toward a $3,500 combined cap.

That's the end of the slides, but I want to add that in the coming months our work on these services will include a lot of additional analysis, looking at the characteristics of the patients likely to exceed the caps on more current data, and using the 1998 data.

We'll also be looking at the length of the outpatient therapy episodes. For example, our initial look into this shows that about 75 percent of patients use these services for less than three months.

We'll look further into the length of the episodes and whether these differ by settings, how they differ by settings, and by different patient diagnoses. And perhaps most importantly, we'll look at the relationship between therapy episodes and the outpatient therapy use and other

post-acute service use.

This work will help us further evaluate the caps and will also yield information that's necessary to move away from a dollar based coverage policy to a policy that is based on prior use of both inpatient and outpatient services and diagnosis.

So at this point, I want to stop and yield to your discussion about either the policies or the future work.

DR. WILENSKY: Let me just ask you before we start, I assume that what we will be doing, at the least, is whatever comes out of the conference bill between the House and Senate as it relates to this issue if it, in fact, includes this issue will also be included as our workplan?

MS. MAXWELL: What were your last three words?

DR. WILENSKY: Assuming that Congress does something, that we will look at what it looks like, the numbers of people who will be affected?

MS. MAXWELL: Yes.

DR. WILENSKY: It's all very nice and good to look at lots of alternatives, but we're about to see which one is the favored alternative.

MS. MAXWELL: Right. For example, off the Senate Finance, we just had off the shelf that it would be 6 percent. But right, whatever they...

DR. WILENSKY: They actually do, I would presume we ought to do more analysis, in terms of wherever they end up, as opposed to looking at all the alternatives.

DR. NEWHOUSE: Stephanie, do you have any information on the degree to which the over the cap amounts are covered by Medigap? That is to say, it would make a difference, at least to me, if this was primarily coming in effect a shift into the Medigap premiums or to employers providing supplementary coverage versus out-of-pocket.

DR. WILENSKY: I think it becomes a non-covered service. We'll find out the answer to that.

MS. MAXWELL: Right when it passed I think a lot people assumed there were going to be conforming changes to the Medigap laws. And as you said, it's considered a non-covered service after $1,500.

DR. WILENSKY: The answer is none.

MS. MAXWELL: Rather than a payment limit.

DR. WILENSKY: But we will establish whether

that's correct.

MS. RAPHAEL: I just wanted to know if in your review of this you understood why speech therapy was originally included with physical therapy, whereas occupational therapy was outside? I'm trying to understand the different variations here.

MS. MAXWELL: Part of the reason about that goes to an arcane detail about who has independent billing. I shouldn't say independent, given the independent/outpatient, but who can bill Medicare as a provider. Speech services can't be billed separately by a speech language pathologist. Their services are usually put, I think, under a physician bill.

That's one reason why that option is a little less of an immediate fix for the Congress. The speech therapist would basically have to be switched over to be able to bill Medicare directly, and there's kind of a lot of administrative work and paperwork that would be required for that to happen, before they can start tallying up underneath the speech therapist.

But those current issues about the physical

therapists being able to bill directly, and occupational therapists being able to bill directly is why there were two caps.

MS. RAPHAEL: I see, speech therapists cannot bill directly. Then my next question was, if the caps were to be raised is there any way of knowing if the rest of those that are now under the cap would end up being increased to the cap?

MS. MAXWELL: Certainly now that P is controlled, given the fee schedule, it doesn't make sense that Q might go up a bit for those people that are clearly beneath the $1,500 amount. We will not be able to really tell that on a unit level given the problems of picking out units of service in the claims. But as the claims come in with the CPT codes on them and the fee schedule amounts we'll be able to have a little more of a comparison in the aggregate payments.

DR. WILENSKY: Presumably, HCFA and/or the Congressional Budget Office will make some estimate about the increased use that is likely to occur when they cost out the implications of changing the cap, because the HCFA

actuary almost always assumes some behavioral change to such measures.

DR. LAVE: I'm curious about how we ought to view the caps. That is, is this a provider rescue or a patient rescue? Because it turns out that -- I don't know whether we think about it differently. You may want to argue that there should be equity across provider types. But I think that if I were somebody -- hospitals I think are more prevalent than these other providers. I make that statement; I don't know. I'm in the middle of being rehabbed. I run out of my $1,500 units. I go to my doctor and I say, oh, me, oh, my. He says or she says, you can go to the hospital and have all the therapy --

DR. WILENSKY: The problem has been the nursing homes.

DR. LAVE: So the problem is the nursing homes. For the outpatient people this really is not a patient protection, except that you like a therapist.

DR. NEWHOUSE: Unless there's only one provider in town.

DR. LAVE: Unless there's only one provider. So I

guess in terms of our analyses should we think about not only it as being a patient condition but also a provider condition? Because as I see it, the majority of people who are being treated on the outpatient side really are unlikely to be much affected by this if most hospitals, in fact have therapy units, or they may think, in fact that it would be a good idea to expand their units because they would have increase in demand.

I mean, it's the same thing with the psychiatric inpatient limits.

DR. ROWE: If I could restate somewhat more concisely, what symptom was this designed to treat? Was this a complaint on the part of providers? Was this a complaint on the part of patients?

DR. WILENSKY: The fix or the original --

DR. LAVE: The fix. I mean, it's a very peculiar fix.

DR. ROWE: The fix, yes.

DR. WILENSKY: I think the concern really was twofold. The biggest concern was that the most vulnerable patients, those who are in nursing homes on Part B services

who had run out of their 100 days of coverage, couldn't beat the system. And the second problem was that you were forcing a change in the person who's providing you with rehab therapy and that that was regarded as not particular desirable and/or you were biasing it toward the use of hospital outpatient.

DR. ROWE: Those were the complaints about the BBA provisions.

DR. WILENSKY: Those were the complaints about the BBA.

DR. ROWE: That are leading now to these changes which we are seeing.

DR. WILENSKY: Right. I think the questions, I guess that we might want to look at is, if there is -- there was a problem that BBA was trying to address in terms of some perceived overuse, particularly in some of these independent facilities or the CORFs. That was why, at least in part -- that was one of the issues that led to the adoption of the provisions in the first place. I think what we're seeing now is a response, particularly to the most vulnerable patients, the ones in nursing homes, who can't

just easily switch providers.

I'm not in a position to evaluate the seriousness of it, but also the complaint of people who were not going to outpatient departments, that they were being forced to switch therapists midstream, so to speak, and that that was not particularly facilitating a recovery.

DR. ROWE: As a clinician, I think switching therapists makes no sense at all. Each patient is different. It takes a long time for the therapist to develop a relationship with the patient in physical or in speech therapy and switching -- I mean, it just doesn't make any sense to me. I think you have to go start at step one at additional expense because it takes a long time to get the assessment and everything else.

DR. NEWHOUSE: Whereas switching the provider is only relevant because of the software glitch.

DR. ROSS: If it had been implemented as passed there wouldn't be the switching; $1,500 was the per beneficiary limit.

DR. LAVE: No, it couldn't have been because the outpatients were always excluded.

DR. NEWHOUSE: Oh, yes, the outpatients --

DR. ROWE: They could always go to the hospital.

DR. WILENSKY: Right, exactly.

DR. ROWE: Not to another outpatient, but they can go to the hospital.

DR. WILENSKY: Right.

DR. KEMPER: I wanted to change the subject so if people have other

DR. WILENSKY: I think we've exhausted this.

DR. NEWHOUSE: We're putting a cap on this discussion.

[Laughter.]

DR. KEMPER: I wanted to come to your last sentence which is that your analysis would provide information necessary to move in the future to a coverage policy based on diagnosis and prior service use. And you also talked about the Secretary's report about this payment. Is the expectation that this is -- I hesitate to use the word interim, but a temporary thing that would be replaced by another payment policy?

MS. MAXWELL: Yes.

DR. KEMPER: Is that required in the BBA or just--

MS. MAXWELL: The BBA says to submit the report.

DR. KEMPER: Is there any sense of what that might look like?

MS. MAXWELL: No. Some people on the Hill are suggesting and requesting that a patient assessment form that would look something like an ambulatory version of the MDS-PAC would be required for these services to help, just as in all the other post-acute services, to have better uniform functional assessment and service and diagnostic tool. But this would be implemented, first of all, to help yield information about the services and the patients, and hopefully to help provide information that would help determine a coverage policy, or at least to help determine coverage norms or standards.

There really was no work done on these before the BBA, so even basically linking the claims and seeing how much of this follows an immediate hospital stay versus follows other services, follows a rehab stay or follows a SNF stay, will be helpful just understanding how much of this follows what kind of service use, and to know the

length of the service use.

Like I said, we have a sense that it's typically less than three months. When we looked at that that was very useful for me to know that, for example, it's not like a home health benefit where there seemed to be some really long, chronic users. Information like that about the service patterns I think are going to helpful in determining either payment policy or some kind of coverage norms. SNF stay

DR. KEMPER: I guess I would urge you to focus at least some part of the effort over the next months on that issue, in part because the cap issue may be solved by legislation, but also so that we're in a position when the Secretary or when HCFA does its report, that we will have had background analysis and be in a position to do more than react to it.

I guess as part of that, the other thing that I keep scratching my head about is how will this payment policy relate to the rehab hospital payment policy. So some thought about that and how substitutable the kinds of therapy are seems to me ought to be part of the thinking

going on there.

MS. MAXWELL: Right, although I would venture that that is true not only following rehab hospitals but also following the SNFs or an acute care.

DR. KEMPER: Yes.

MR. MacBAIN: On page 8 of the paper in our books which begins the discussion of Medicare payment policies there's a list of things that Medicare does not pay for; services performed repetitively to maintain a level of function where the potential is insignificant for improvement, goals will not materialize, that sort of thing, which would seem to exclude a whole category of people who otherwise might be receiving therapy services.

My question is -- two questions. First of all, can we determine the extent to which these definitions are actually applied? Secondly, if they are being applied, does the cap really add anything, or are we eliminating coverage for people who really are benefiting from the services, by putting the cap on it?

MS. MAXWELL: Let's see if I can remember all the parts of your question.

MR. MacBAIN: The first part is, do we know whether the Medicare definition is actually being applied in the payment of claims?

MS. MAXWELL: This is where some of the OIG and GAO reports where they actually go into medical records are finding some therapy that they consider to be not under the coverage rules for skilled --

MR. MacBAIN: That's the 13 percent.

MS. MAXWELL: Right. Those are services -- when they don't meet those definitions for the coverage policy, coverage for skilled therapy, and if it doesn't meet those it's considered maybe perfectly appropriate for the patient not under the skilled therapy coverage rules. If it's a SNF patient, it would be considered to be maintenance therapy that should be by -- oftentimes those are by nurse providers rather than therapist providers.

MR. MacBAIN: What I'm trying to get at is whether the cap is cutting fat or muscle. If in fact the fat, at least in Medicare terms, has already been eliminated by the benefit coverage rules, does adding a cap on top of that cut into efficacious therapy?

MS. MAXWELL: I think the coverage rules themselves do not cut out the fat.

MR. MacBAIN: Okay. You said as you get into this you'll try to get into some qualitative data about what types of patients are in that 14 percent or 6 percent or whatever residual we end up with, so hopefully that will give us a better sense.

DR. WILENSKY: Thank you. The next session is on the home health workplan. Thank you, Stephanie.

Louisa?

MS. BUATTI: Last month I presented some preliminary background information on HCFA's research for developing a home health prospective payment system. This month's paper provided more detailed information from a recently released report on the demonstration projects. Today, I'd hoped to share with you some more details of HCFA's proposed system but they have not yet issued the regulation. So today my presentation is going to focus on the workplan the staff has planned for this coming year. We'd appreciate your comments on it, and afterwards we'd be happy to try to answer questions about the demo results that

were summarized in the paper.

As you know, the current Medicare law requires HCFA to develop and implement a case-mix adjusted prospective payment system by October 1st, 2000. The payment rates established under the PPS will be calculated so that they're budget neutral to the spending level as if the current IPS limits were reduced by 15 percent. As you may have heard, the Congress is currently considering phasing in this reduction.

DR. LAVE: This is a 15 percent reduction over the reductions that are involved in the interim system?

DR. NEWHOUSE: Right.

MS. BUATTI: Yes. This year we've planned three analyses concerning home health payment issues that will likely form the basis of the March report recommendations. I'll just quickly summarize them.

First, we'll evaluate HCFA's proposed rule for the PPS and prepare a comment letter to the Secretary. Then we will prepare historical 60-day payments to the proposed payment rates under the PPS. Then third, we will examine changes in home health use over time. Now I can describe

the different analyses a little bit more specifically.

There will be a number of issues raised in the comment letter to the Secretary that the Commission has already identified. Last month, some of the commissioners were concerned about the generalizability of the demonstration projects HCFA has conducted, particularly because the demonstrations were conducted, some of them were conducted prior to the implementation of the IPS and the PPS rates will be based off of IPS levels.

Another issue is the ability of the case mix adjuster to predict resource use, particularly because there appears to be great variation among home health users.

The Commission also expressed interest in the size of the payment unit and the need to develop special payment provisions for cases that were extreme in terms of cost.

Another issue that will likely be addressed in the comment letter involves the implementation of the PPS itself. Currently, all home health agencies are scheduled to begin PPS on October 1st, 2000 rather than being phased in by their cost reporting periods.

In the June report last year, the Commission

stressed the importance of providing information to beneficiaries, home health agencies, and fiscal intermediaries so that misunderstandings about payment policies do not impede access to care.

In addition, the Commission has indicated that HCFA should develop policies to monitor access and quality of care for all home health, for all post-acute providers as they move to a prospective payment system.

Then the final issue that you've identified is that as with all payment systems based on patient classification will be important to monitor changes in case mix over time.

The second analysis that we have planned is a comparison of the PPS payment rates for 60-day periods of time with the payments that occurred for 60-day periods of time prior to the PPS. To compare payments before the PPS implementation we will construct 60-day episodes of care and some charges for services provided during each of the 60-day periods. The charges will then be adjusted using cost report information to estimate Medicare payments.

Because the comparison periods do not include case

mix information we'll not be able to compare payment rates for specific types of patients. Instead we will compare the distribution of payments before PPS with the distribution of payments under the proposed prospective system. In this analysis we'll compare the percentage of home health users in each of the payment groups under PPS with the share of users at different payment levels before PPS.

I see some puzzled faces. An example would be that if you're looking at payments in 1994, if 20 percent of the patients received care costing Medicare X dollars in the course of 60 days and under the PPS only 5 percent of the patients would receive payments of X dollars, then you could compare those and you might come to the conclusion that the new payment system may not support a level of care that was provided in 1994, for example.

The third analysis we have planned this year is to examine home health use over time. This will provide us with baseline information to evaluate the PPS. We'll look at visits per user and mix of services per user in 1994; the base period that was used to calculate the IPS payment limits. We'll also look at 1997, the final year for cost-

based reimbursement for home health agencies, and then 1998 which was the first year of the IPS and the latest date for which we'd have a full year of data.

As you'll recall, we attempted to do this analysis earlier this year but we had to put it on hold when HCFA started to investigate the validity of the data. So we're really to attempt that again.

Now I'll turn it over to you for questions and comments.

DR. LAVE: I had a question. One of the things that several of us have been very concerned about with moving to episode-based payment would be the incentives to increase the number of episodes. I looked at the evaluation of the case-based PPS and noted that they found that the cost per episode had decreased but there was no comment about the number of episodes. Do you have any information what happened to the number of episodes under the demonstration?

MS. BUATTI: Unfortunately, I don't have that with me. I know that HCFA is concerned about that in that currently they have not yet addressed the issue of payments

across multiple episodes. For example, for patients who continue to fall within the same case mix category. But that's something that they intend to address in the --

DR. NEWHOUSE: It's not just that. It's the potential for patients who had no episode before to have an episode.

MS. RAPHAEL: In the paper that you wrote, which I thought was very informative, I was interested that you said one of the results of the demonstration was that cost per visit went up and that you thought small agencies were potentially imperiled. I was just interested in that finding.

MS. BUATTI: That was the finding of the evaluators, that the smaller agencies had more difficulty reducing their cost per episode, and the cost per visit for those agencies tended to increase more than for larger agencies.

DR. NEWHOUSE: Louisa, I just want to first just clarify terminology. I tend to be concerned about what I'll call left outliers and right outliers, meaning the very cheap people and the very expensive people. I think that's

probably better terminology. Were you using inlier to mean what I mean by a left-hand side outlier?

MS. BUATTI: Yes.

DR. NEWHOUSE: An inlier to me is somebody that's not an outlier. That comes up in the SNF chapter, too.

Then I suggest we consider, possibly for the June report, the issue of what kind of -- assuming that HCFA goes ahead with what they're talking about -- what kind of monitoring system one would put in place, particularly given the concerns about the very small and very large episodes. We don't have to do that until they make their reg final, but we might start to think about that at least.

DR. WAKEFIELD: Just a couple of comments. First of all, I don't know if you've seen, Louisa, Project HOPE's September report on implications of the BBA for rural hospitals but it's -- rural hospitals owning home health agencies, that relationship. My concerns are tied to access to home health services, again primarily for rural beneficiaries.

Just as an aside, what their data seem to suggest is that about 54 percent of all rural hospitals own a home

health agency, and they compare that to about 41 percent of urban hospitals. And that, no surprise, the size of the home health agency is smaller on average than its urban counterpart, needless to say.

The couple of comments that I have, actually one and this I guess relates to the report you were just referencing that was not done, the study that was not done by you. I'd be interested in knowing, you're citing on page 3 the evaluators talking about -- evaluators suggesting that given the small agencies problems, small agencies may find it in their best interest to merge with others to achieve more favorable economies of scale. I'd be interested in knowing with what or whom or where that those agencies would be encouraged to merge with, when one thinks about access to home health services and agencies in rural areas, just as an aside.

Now to my real points. On page 9, you're talking about what the analysis would describe, and I just want to reinforce your selection of the variables that you've included there. Analysis would describe the number of visits or volume, because volume from my perspective is an

extremely important issue. Also, you mention, obviously, geographic region. I'm wondering, will that include -- when you're looking at geographic region will that include -- or maybe you can't capture it, but could you capture the service area for a home health agency. Apparently not by the look you're giving me.

Cut to the chase. The reason I'd be interested in that obviously is because if it's a large, large service area then there are transportation costs that may not be picked up in the prospective payment. But if you can't capture that, it's just a point.

I'll just real quickly, because I don't want to take up too much time, run through a couple of others. The provider ownership, are you thinking in terms of examining provider ownership there? Are you looking at profit versus non-profit?

MS. BUATTI: Yes. And whether or not it's a government agency as well.

DR. WAKEFIELD: Public or private. Okay, so profit versus non-profit. I guess that's --

MS. BUATTI: And then there's a separate variable

that allows us to distinguish between freestanding or facility-based.

DR. WAKEFIELD: Thank you, that's the other one I was looking for was hospital versus freestanding. So you're going to look at that, too.

MS. BUATTI: Right. There are also some home health agencies based in SNFs and CORFs. But very few.

MR. MacBAIN: First, thank you, Joe, for clarifying the inlier-outlier thing because I was a little confused by that, too. In talking about short stay or left-hand outliers, it would be helpful if you could give us a graph showing the distribution, because at least as I envision the graph it's with most of the left-hand outliers clustered just below the trim point, where the right-hand outliers stretch out on a long tail, which suggests to me that there's an opportunity to bump somebody from a left-hand outlier to an inlier relatively simply compared to having a large effect on bumping somebody from an inlier to a right-hand outlier. I'm just concerned about behavioral response to an inlier to a left-hand outlier trim point.

MS. BUATTI: The model that was described in the

latest case mix study considered the left-hand outliers those, I guess up to four visits. So it appears that -- again, nothing is final but it appears as though the case mix system would begin to count the 60-day periods with those greater than four visits and they would treat the first four visits somewhat differently. Although again, that hasn't been announced, but that was something --

MR. MacBAIN: But the incremental revenue for that fifth day could be substantial. That's my concern.

DR. KEMPER: I'm not so clear why we want to focus just on the outliers. In the sense that there's an incentive to reduce a day anywhere along the continuum, and the last thing we would want to do is introduce these notches, I would think, although there's obviously a notch at zero and that's why we're concerned about the left-hand. But it seems to me you would want to --

DR. NEWHOUSE: Or maybe at five.

DR. KEMPER: If you make it four, then it's at five. If you make it at five -- so you'd want to have some sort of smoothening. So I don't know whether some sort of cost sharing or risk sharing here is appropriate or what.

But it's not obvious to me we want to just focus --

DR. NEWHOUSE: We should probably wait till we see the rule till we speculate further. I mean, the general principle is clear.

DR. KEMPER: Or the concern is clear.

DR. NEWHOUSE: Yes, the concern is clear.

DR. KEMPER: I guess the other question, I didn't understand your data analysis and how you could evaluate the proposed system without having case mix data.

MS. BUATTI: That is somewhat of a challenge. We're working to get some information from HCFA on case mix information that they used to develop the system.

DR. KEMPER: So you're going to try to get those data. But what you proposed is something without using those?

MS. BUATTI: Yes.

DR. KEMPER: That I didn't understand. Maybe we should talk about separately. Maybe that's a better way to do it.

DR. NEWHOUSE: Anything else on home health?

Thanks, Louisa. Let's recall Stephanie.

MS. MAXWELL: This has been a pretty busy summer in terms of policy decisions and developments regarding the rehab PPS. There's also some major study initiatives that go underway this summer regarding potential long term hospital PPS systems. The point of this presentation is to summarize these decisions and activities and to briefly review our work in these areas in the coming months.

I want to start by showing what the BBA said about the PPS for rehabilitation hospitals. It noted what types of factors should go into the classification system, but unlike the case with the SNF PPS, the BBA left the choice of a classification system up to HCFA.

It also noted the payment adjustments that will be used. Regarding the adjustments, it specified a 5 percent outlier pool, which by the way is the same size as the outlier pool used in the acute care PPS. It also specified that the market basket would be the basis of the update for inflation. Finally, the system is begin its phase-in next year in October of 2000.

Until this summer, HCFA was in the initial steps of developing a rehab PPS that entailed using the same

methodology that was used to develop the SNF PPS. So along those lines, HCFA contractors began work in the spring of this of '99 of a study to collect the patient assessment and resource utilization information necessary for designing the classification system and a set of weights.

You probably remember this from our presentation last year, information was to be collected on approximately 2,000 rehabilitation patients. The patient assessment instrument used in the SNF PPS had been modified to make it more applicable to rehabilitation hospital patients and information was going to be collected on patients in the rehabilitation study using that modified instrument. Resource use was going to be measured on a per diem basis mainly by counting the minutes of clinical staff time spent with patients.

In our March report the Commission raised several concerns about each of these four points. We were concerned about the reliability and validity of a PPS based on 2,000 patients, which is less than 1 percent of Medicare's rehabilitation hospital patients in 1998. Other concerns stemmed from how the PPS methodology handles rehabilitation

service use, at least in the SNF system. SNF patients who use rehab services are assigned to a RUG based on the number of minutes of therapy they use and then by their ADLs.

Another issue echoes some of the current problems of the SNF PPS by relying mainly on the count of clinical staff minutes to develop the payment weights. We were also concerned about whether the method would sufficiently capture the costs of other hospital service use like drugs and lab work.

Finally, the Commission was somewhat concerned about the appropriateness of a per diem unit of payment for patients undergoing inpatient rehab which is quite a functional outcome oriented, intensive course of rehab care. I say somewhat concerned because both in the policy community generally and in the Commission there were different opinions about this and a health sense of the pros and cons about a per diem and a per-discharge payment unit.

In the end, as you know, we recommended in the report that the Secretary refine the FIM-FRG system, which is another rehabilitation PPS proposal that HCFA had already developed and evaluated under a prior contract.

In the spring and summer there were mounting pressures and discussions about the PPS options among and within HCFA, the department, the Congress, and the rehabilitation hospital community. In July of this summer, HCFA announced that it would alter the course regarding the PPS. As a result, the rehab PPS is being finalized this fall and a notice of proposed rulemaking is expected by January of this coming year.

HCFA's contractors using Medicare cost report data, Medicare claims data, and patient assessment information for 1997 to update and refine the classification groups and payment weights that it had refined before on the 1994 data of the FIM-FRG system. The patient classification system uses function and diagnosis to group patients. Patient weights are derived from Medicare payments, and the unit of payment is the discharge.

The contractor will also revisit and refine other payment system adjustments that it had modeled on the '94 data, particularly regarding transfers, inliers, or short stay outliers, and outliers in the more traditional term, the long stay outliers, GME payments, DSH payments, and wage

adjustments.

The work regarding the transfers will be especially reevaluated. In the '94 evaluation, transfers to PPS hospitals were evaluated, whereas the current work investigates those transfers as well as discharges to other post-acute settings. This broader definition of a transfer and the use of transfer and short stay adjustments are key parts of the Commission's recommendation about this policy proposal. These policies, about the transfer and short stay outliers are also supported by HCFA.

In an important addition to refining the FIM-FRG proposal, HCFA reoriented its original rehabilitation staff time or RUG study. Now that study is focused on collecting detailed patient information on a few diagnostic conditions that do not occur frequently among the Medicare population. The main ones that they're looking at at this point are traumatic brain injury and burns. That information will be used to help refine the classification groups and the payment weights applicable to the patients with those conditions.

HCFA is also currently working on software that

the rehabilitation hospitals and units will to assess and classify the patients for PPS payment.

DR. LAVE: Can I ask a question about the one which says they're going to use the FIM-FRG and then the last one that says they're going to use the MDS-PAC? I don't understand that.

MS. MAXWELL: The final classification groups and payment weights will be derived from FIM classification, FIM assessment information which is available on most of the Medicare patients through the system that we've talked about in many of the presentations last year. Most of those items within the FIM are, to most people's perspective, very closely integrated into the MDS-PAC. So the MDS-PAC will be used to assign the patients once the system is implemented and that is different and much more extensive information.

DR. NEWHOUSE: I think this is like saying you're going to use the face sheet to assign the DRG, or the information on the face sheet to assign the DRG. You're getting the functional status from the MDS-PAC and then you're going to use the functional status to classify.

DR. LAVE: But then they're saying they're using

the MDS, unlike they're mapping the FIM-FRG to the MDS --

DR. NEWHOUSE: No, it's the other way around, the MDS maps -- that information gives you the functional status which goes into the FIM-FRG.

MS. MAXWELL: From the MDS information, patients will fall into the classification groups.

DR. KEMPER: Because I thought the FIM-FRG was more detailed than the MDS; that there was more information.

DR. ROWE: FIM-FRG is different than the minimum data set.

DR. KEMPER: That's what I'm having trouble with.

DR. ROWE: It includes some patients characteristics that are derivative of the minimum data set.

DR. KEMPER: It's the clinical stuff that I was concerned about.

MS. MAXWELL: There's much more clinical information in the MDS. So the MDS includes the items that are in the FIM plus a whole bunch of other stuff.

DR. LAVE: And there's nothing in the FIM that's not in the MDS?

DR. NEWHOUSE: I don't think so.

DR. KEMPER: I thought it was the other way around.

DR. ROWE: It's the other way around.

DR. LAVE: So you can use the data from the MDS and put people into the FIM-FRG categories?

MS. MAXWELL: Yes.

DR. LAVE: So the MDS is like the ICD codes and the FIM-FRG is the DRGs.

DR. NEWHOUSE: The MDS is like the face sheet. This has the information that you're getting.

She's got a slide here. Here's the next slide. Nice segue.

MS. MAXWELL: This just lists all of the sections on the tool. This is slated to go online, of course, by October of 2000 in facilities. HCFA is working on the software that facilities would use to assess the patients using the MDS, and the information on the MDS would lead to what groups within the classification system that they would be assigned. HCFA's also hoping actually that this would be available before October of 2000 to facilities just so that they can increase their familiarity with it before payment

actually turns on it.

In the interest of time I just want to show you this overhead about analysis we plan to do, although we can come back and discuss it if you like. Basically, we want to mine the claims that are on some of these points and we have to comment on the Secretary's proposed rule which, as I mentioned, will come out in around January.

Some of the particular points of the analyses will be to look at the patterns of discharge to different post-acute sites, transfer patterns, and the length of stay of the very short and very long stay patients, and the cost patterns of the very low and very high cost patients.

If there's no particular questions about the rehab I'll just move on to the long term hospitals. First I want to call your attention to the appendix in the materials which has some background on long term hospitals. Today though I'm going to go straight to the PPS issues.

The BBA does not require implementation of a PPS for these hospitals. It does require though that the Secretary develop and submit to the Congress this month a proposal for legislation that would establish a case-mix

adjusted PPS for these hospitals. The BBA states specifically that the Secretary shall consider several payment methodologies including the feasibility of expanding the current DRG groups and PPS for acute care hospitals to payments under the Medicare program to long term hospitals.

About the report, an interim report to the Congress is expected later this fall and a final report will be released next summer. HCFA staff tell us that the interim report will provide background information about the TEFRA system and about long term hospitals and hospital patients and will describe their overall workplan to compare and evaluate potential PPS approaches for these hospitals.

This summer, HCFA contractors started to evaluate the potential PPS options. Again, the work in that evaluation will be the basis of the final report in the summer. HCFA and its contractor are evaluating comparing all of the known approaches or concepts for long term hospitals. These include three options or types of options.

The option that at this point is the most fully specified is a PPS that is methodologically quite similar to the acute care PPS. It proposes using 179 DRGs to which

long term hospital patients are most commonly assigned, plus an additional assignment groups that combine long term hospital patients in other DRGs into similar cost categories. Payment weights for those total 184 groups were developed using Medicare charges for long term hospital patients.

This method predicts about 40 percent of payments assuming a 5 percent outlier pool, which is the outlier pool in the acute care PPS system and required for the rehab system. It predicts about 60 percent if you use a 10 percent outlier pool. With no outlier pool it predicts about 20 percent. Just for comparison, the current TEFRA system that these facilities are under predicts about 15 percent of payments.

The second option and the one that the BBA states must be explored is to simply expand the acute care DRG system. In other words, instead of creating a separate PPS as this first option does, this second one would add some number of DRGs for long term hospital patients to the current DRG system.

DR. NEWHOUSE: How does that differ from a

separate system operation?

MS. MAXWELL: It would not be a separate system. For example --

DR. NEWHOUSE: Why don't you go ahead?

MS. MAXWELL: There are a lot of particular models that the second option could explore. Obviously, even just the number of DRGs that would be added could be explored empirically, and HCFA contractors are going to explore that empirically and they'll be able to compare that with the first option.

The contractors will also evaluate and compare those two options with a third approach, kind of a per diem, RUGs-like PPS approach. HCFA had expressed a preference for this third approach in the past, but it certainly has not begun a long term hospital patient study that would be necessary to develop a per diem RUGS-like PPS. This third approach just would allow a conceptual comparison with that, whereas the first two approaches there will be empirical comparisons available from the study.

I just want to show you the analyses that we plan to do, although again we can come back to this in the

discussion. In the coming months, our work in the long term hospitals will include the quantitative analyses to address some of the issues about long term hospital patients and care patterns, and qualitative analyses about the PPS approaches.

We plan to do some targeted comparisons of long term hospital patients with others such as PPS outlier patients and selected SNF patients, and also further analyze the care and expenditure patterns of long term hospital patients. This will help answer questions such as whether long term hospital patients have fewer readmissions or lower mortality rates and lower overall costs than patients who are in areas where there are no long term hospitals. There's about 230 of those in the country. So certainly not available for all patients.

Of course, we will comment on the Secretary's report once it's released next summer. At this point I'll yield to your discussion about the PPS approaches or about the workplan.

DR. WILENSKY: Thank you. Joe?

DR. NEWHOUSE: A couple items, Stephanie. To come

back to the question I started to ask. Would the expanded DRG option be only open to long term hospitals? Or if I'm a short term general hospital can I bill an expanded DRG, in a new DRG?

MS. MAXWELL: Both of those would be expressly looked at, having additional DRGs that only long term hospital patients can go into versus if an acute care hospital did have a patient that fit that length of stay and fit that DRG. But they're both empirically tested and I understand that --

DR. NEWHOUSE: The former would seem to have no functional difference with a separate system.

DR. ROWE: I'm sorry, I didn't understand the answer.

MS. MAXWELL: The question is whether or not if you tacked on some additional DRGs to the current system, would those DRGs be available only for long term hospital patients.

DR. ROWE: I got the question. It was the answer I didn't get.

MS. MAXWELL: As I understand it, the contractors

are going to look at both. Look at what happens if you just have additional DRG groups for the long term hospital patients, but they would also see whether or not other --

DR. NEWHOUSE: So if I'm a short term hospital, do I have then the option of billing as an outlier or billing in this new DRG, since the long stay patients would presumably mostly be outliers, or a lot of them would be? Or is that too fine a level of detail for the present level of discussion?

MS. MAXWELL: All of the questions have been thought about and raised by HCFA and the contractors and they're going to look at it. But as I understand it, the original assumption is that they would be DRGs just for the long term hospital patients.

DR. ROWE: Can I comment on that before you go to the next question? I think there's a principle here that goes beyond this particular set of institutions and services, and it goes into others. We spoke last year about cancer hospitals versus cancer patients at general hospitals who would be getting exactly the same care. We've spoken about the PPS-exempt hospitals, psych hospitals, for

instance, versus a psych unit in a given hospital. Depending on how the lawyers want to help you, you can create a hospital out of a couple floors of your hospital if it's financially advantageous.

I mean, I think it's silly. I think we should be thinking about the beneficiary who's getting the services and not try to foster these distinctions based on the title of the facility. It should be what the beneficiary needs and what the beneficiary is getting. If somebody is getting care in a general hospital and they have cancer, then Medicare's payment for that should be more or less the same as somebody across town in a cancer hospital.

DR. NEWHOUSE: The problem with that for this is, these institutions are defined by having an average length of stay greater than 25 days. So by definition the PPS doesn't fit them.

DR. WILENSKY: That's why they were excluded.

DR. ROWE: I understand that.

DR. WILENSKY: We can come back -- we actually have this discussion in our report. We, as a general principle, have clearly preferred having the payment for the

service not differ according to the facility. When we made a recommendation last year about a demo that would pay rehab services provided in a nursing home like rehab services provided in a rehab facility, it was to try to not have the payment tied to the facility but really to the service provided.

But there are some areas traditionally which have eluded the ability of HCFA for defining a prospective payment system, and since its inception, psychiatric and long term hospitals have been two of the four that have been excluded. We can continue this discussion --

DR. ROWE: I know that and -- that's fine. I think psychiatric services and psychiatric hospitals is a question.

DR. NEWHOUSE: But if you think about it, here you've normed it, in effect, on an average length of stay in short term hospitals. So now you've got long stay patients that -- let me go on the workplan.

At the very end of the workplan you propose basically comparing readmissions and mortality rates among long term hospital patients -- this is page 8 -- with

patients in other post-acute settings, and extended stay SNFs. I'd be very skeptical about the ability of that analysis to be convincing. The case mix controls would have to be better than I think they're capable of being. We know these hospitals are a very heterogeneous group of hospitals and the patients in them are very different. To think that -- I just wouldn't know what to make of a comparison on readmissions or mortality rates in either direction here given that I don't have any confidence in the ability to control for case mix.

DR. KEMPER: I had the same reaction. There's just such a selection into these hospitals.

MS. MAXWELL: Absolutely point taken. The closest we could get at this would have been to take selected DRGs as assigned and the PPS hospital, given that those DRG assignments are the most --

DR. NEWHOUSE: No, I assume we're going to do DRG. But even so, it doesn't help enough.

MS. MAXWELL: And then look at the share of payments for non-therapy ancillary services, look at very specific patients like vent patients which are a little more

definable than a patient that is in some of the other diagnoses, some people think. But basically by trying to look at the highest end patients in some of the other settings, highest end regarding their non-therapy ancillary use, we were just trying to have some kind of a longer term pattern of care look among the long term hospital patients and then just look at an area where there are no long term hospitals at all. The PPS outlier patients, that's at least a start of a group.

DR. NEWHOUSE: In epidemiological terms, that's an intent to treat analysis. But in terms of saying anything about the long term hospitals, that's going to depend on having a fairly high proportion of these patients in some area in the long term hospital. I'm not sure you've even got that. But maybe now we're getting past what I really know about this area; you know, how concentrated vent patients in long term hospitals? I suspect there's a number of them in short term general hospitals so you're not going to have much power in your analysis. I don't know.

MS. MAXWELL: We have a 100 percent universe of the long term hospital patients, so certainly with the ones

that specialize in vent patients we would at least have the biggest number. But I take your cautions.

MR. MacBAIN: Just to follow up, Gail touched on our recommendation last go-round to try to deal with the same patients the same way regardless of whether they're being treated in a rehab hospital or a SNF. Do you have a sense of how much that overlap is, and were you planning to revisit that recommendation in your analysis? What difference there is between paying on a FIM-FRG basis in a rehab hospital versus the same kind of patient being paid for on a RUG basis in a SNF?

MS. MAXWELL: For many of the -- we think there's an overlap in some of those patients, but not all of them. Just even the three-hour rule for rehabilitation hospitals tells you that they're getting the sickest rehabilitation patient. The therapy minutes within the RUGs system generally aren't focusing on minutes that would take you into that three-hour rule but would reflect a much less intensive therapy course. I think as we have actual RUG assignment information on the SNF claims in the future it will help us compare that more than the information we've

had in the past.

DR. WILENSKY: Any other comments? Jack, to go back to the issue that you raised, when we come to discussing this further in the actual chapter for March I think it will be appropriate either again as we look at the general areas where we have cross payment or different payment areas to try to raise our concern when we pay for things differently by the facility. I do think that the averages, as Joe mentioned, the averages here are such that the payment based on averages in the acute care make it really problematic to think of them in the same way.

I do think the burden of proof ought to be on the institutions that claim that they are different. And in this case, I think they actually have met that. It is not clear whether or not the same is true for some of the cancer examples that you have raised earlier as to whether the cost of care of treating cancer patients in an acute care hospital like yours is fundamentally different than the cost of care of treating cancer patients in the cancer facilities.

I think that the notion of saying that the burden

-- if units, if institutions claim that they are fundamentally outside of the averages in a significant and prolonged way, it would be appropriate to say the burden of proof of that ought to be on these institutions. But I think in this case the PPS-exempt, the four PPS-exempt actually have demonstrated that in the past.

DR. ROWE: Yes, I think this is an interesting policy question, and is often the case, you know more about this than I do and that's fine. I think that with respect to the psych hospitals, the facts are that if you go to many large, acute general medical hospitals there is a psych building which is a separate building and is in fact no different than if it were sitting there as a "psych hospital."

DR. NEWHOUSE: The analog here is the so-called long term hospital within the hospital, which HCFA has tried very hard to stop and mostly has succeeded.

DR. ROWE: I understand. So there's that, you see. Just like the children's hospital. All the big, medical surgical hospitals have children's wings or separate buildings. Go to Columbia Presbyterian, they have a babies'

hospital as part of Presbyterian. How is that different than the Children's Hospital of Philadelphia? That's my question. And we'll discuss it maybe if we have a chance of if there's some reason to someday, and there may be exceptions.

DR. WILENSKY: I'm very sympathetic with the issue that you're raising. I would regard this appropriately as saying, the burden of proof of indicating a difference ought to be on those that are claiming a difference, as opposed to presuming a difference because they have a different name. We can, as we get ready for our March report, try to pursue that in areas where we think we have something to say about this. So I am quite sympathetic with the issue that you raise.

MS. MAXWELL: Also, remember the psych units as well as the rehab units of these acute care hospitals are exempt from the PPS. Those units as well as the freestanding hospitals are under this TEFRA payment system. As Joe was saying, in theory there's not supposed to be these unit equivalents for long term hospitals, but those units are exempt.

DR. ROWE: I understand that, Stephanie. I know they're exempt. But I also know that if you look at the House Ways and Means Committee proposal, it says PPS-exempt hospitals. It doesn't say PPS-exempt units. So it's differentiating the hospitals from the units. And if that's what's going to happen, then that's in appropriate.

DR. NEWHOUSE: I don't think so.

MS. MAXWELL: That's a technical --

DR. WILENSKY: Jack, don't put so much into this summary. I'm not sure that that's correct.

DR. ROWE: Okay. But I think there is -- I know that those are exempt. But I think there are a whole bunch of issues of peds, cancer. There may be other things coming along down the line -- I don't know -- and we just should have some principle. We had one here that didn't make sense to me either which is, you can get as much rehab as you want if it's in the hospital but you're limited if it's an outpatient. There's another one. I mean, there's like 100 of them and we just need a general discussion of them.

DR. WILENSKY: No, I agree and I think we will try to make -- when we get ready for our March report, to raise

this specific issue. But these summary statements of legislation they're putting out, and I don't think there is a distinction intended in that.

Thank you, Stephanie. Deborah?

MS. WALTER: The purpose of this presentation is to provide an overview of the proposed workplan to assess the impact of the BBA on SNF utilization patterns. The analysis may guide decisions on where, if any, targeted fixes should be made, and to provide some preliminary data that may begin to address where refinements to the SNF PPS may be appropriate.

I'm seeing the commissioners' comments on whether the appropriate questions have been raised in the analytic framework and any areas of concerns or issues that should be considered in conducting the analysis. I'll begin with a brief overview of the changes to Medicare payments to SNFs followed by the broad policy issue, and then the workplan itself.

The BBA made significant changes in Medicare payments to SNFs. It established a PPS under which SNFs are

paid a single case mix adjusted per diem rate for each resident that covers all routine and auxiliary capital related costs, and the cost of Part B services provided during a beneficiary's Part A stay. Previously Medicare paid most SNFs a daily rate based on their reasonable costs. However, therapy and non-therapy ancillaries were not subject to those limits.

The PPS began to be phased in on July 1st, '98 for each SNF according to its cost reporting period. Under the SNF PPS, rates are case mix adjusted based on the classification called the resource utilization groups, version III, or RUGs. RUGs-III is intended to reflect treatment costs associated with a full range of SNF patient types with varying characteristics and degree of resource intensity.

Several studies, including those funded by both the industry and HCFA suggest that the RUG-III payments may be too high for patients who use relatively few non-therapy ancillary services and too low for those who need relatively high levels of these services. This may be due to the fact that non-therapy ancillary services were not included in the

development of the payment adjusters or weights that raise or lower the average payment to account for the resource need differences across patients.

Inadequate payment rates could potentially result in SNFs denying admission to beneficiaries who have medically complex cases, or not receiving the necessary services. HCFA is funding substantial research to examine the potential for refinements to the SNF case mix methodology, including the examination of medication therapy, medically complex patients, and other non-therapy ancillary services.

We expect research findings to be out by January 1st, 2000, and if the research supports the refinements, implementation is expected on October 1st, 2000 with the update to the PPS rates.

Since the time of writing and that you've received your materials, the GAO published a report related to the non-therapy ancillary cost variation. Essentially, it concluded what the other studies have already concluded, that the PPS case mix adjustment method may not appropriate account for the variation in non-therapy ancillary costs.

But I think more importantly, the report suggests that increasing SNF payments for all or some RUG groups will not address the allocation problem. Rather, it would just simply add cost to the program and increase overpayments without improving the distribution of payments across patient categories and SNFs.

Moving on to the proposed workplan. We are proposing a pre-post approach. The pre-PPS period will look at the data for facilities and beneficiaries served for fiscal years '95 through '97. The post-PPS period will include the same units of analysis for fiscal year '98. To minimize confounding effects resulting from seasonal variation and differences in periods among facilities who may be transitioning to the new payment system, the analysis is proposed to focus on the last fiscal quarter; that is, October through December of each of the study period years.

Facilities beginning PPS in calendar year '98 will be compared to those providers who did not start in '98. This effectively serves as our control and test group, and obviously we're interested in any differences between those two groups.

In addition, MedPAC proposes to convene a clinical advisory panel. This panel will meet twice, once at the beginning of the project to review the detailed workplans and to provide expertise regarding clinical indicators most relevant for the analysis. Then again we'll bring them back after the completion of our analysis to assist in interpreting some of the findings.

The research will proceed in two phases. Essentially, phase one will focus on the number of skilled nursing facilities and changes in case mix. We plan for this analysis to be completed for the March report.

Phase two will focus on the longer term, more complex issues that will require more time and information to begin to evaluate. In the latter phase we will attempt to more specifically address whether payments are appropriate. We hope to have this work finished for the June report.

The first question addresses the change in the number of SNFs. This is a fairly straightforward analysis. Widespread provider withdrawal from Medicare could suggest that Medicare's payment rates are too low. On the other

hand, relatively little change may suggest that payments are adequate, or that it may just simply be too early to detect any changes in provider behavior.

The second question looks at whether facilities have changed their case mix since the base year. Prior analysis has shown that the post-acute care utilization is strongly related to the beneficiary's inpatient diagnosis. Approximately 13 DRGs account for half of all post-acute care use in the SNF setting, while an additional 11 DRGs make up much of the remaining component. Since we don't have complete RUGs data -- it's just not yet available -- we're proposing an indirect measure to examine this area of interest.

The analysis will be limited to patients within the 24 DRG assignments, and from this inpatient pool patients that had a SNF stay will be selected and then linked back to their assigned DRG for their qualifying hospital stay. This approach will allow us to compare non-users of SNF to SNF users.

In order to more accurately assess whether facilities have changed their case mix over time, APR-DRGs

will also be assigned to all patient records with those 24 DRGs prior to the SNF stay. The analysis will use these assignments made during the hospital stay as a proxy for the clinical characteristics of SNF patients and expected services that comprise the SNF stays.

As you may recall, the APR-DRGs were discussed at length by MedPAC staff at the September meeting in relation to the work that they were doing for teaching hospitals. But very briefly, the APR-DRGs are intended to more accurately account for differences in patient severity of illnesses. Instead of differentiating patient categories based on the presence or absence of comorbidities or complications, the APR-DRGs groups patients based on the presence and the level of the comorbidities or complications.

The importance of a particular secondary diagnosis varies according to the nature of the patient's problems, including the underlying condition, age, and the presence of certain operative procedures. So the secondary diagnosis might result in different severity class assignments depending on other characteristics of the patient's

condition or treatment.

We're also proposing to examine changes in the case mix index during our study period based on the APR-DRG weights. I think that this is of interest since it provides an estimate of acuity by relative costliness of hospital inpatient care compared to the overall costliness across all APR-DRGs.

Finally, we'll look at the length of stay examined by the APR-DRGs for each year.

Finally, the last two questions will be addressed for the June report. We plan to limit our analysis to approximately five types of patients which reflect the higher acuity levels. We're hoping that the clinical panel will provide some insight and guidance in this area. For this particular question we will use the DRG and the APR-DRGs, and changes in SNF services and procedures associated with these patient groups, pre and post-BBA will be examined using claims data.

For the fourth and final question we'll identify five or 10 costly services with the assistance of our expert panel. Based on their input, procedure and drug codes may

be used to assess changes in the number of costly services provided to SNF beneficiaries pre and post-BBA.

That was a real quick overview and I now turn it over to you for discussion.

DR. ROWE: One question. Deborah, the last item on one slide went past me pretty quickly on the length of stay. Do you have the length of stay data on both the hospital and the SNF stay?

MS. WALTER: Yes, we will. But I think the plan, I think of particular interest is to look at the length of stay on the hospital side, because of course, we're hearing that the more medically complex are staying longer on the hospital side before actually going to the SNF side. So by looking at the APR-DRGs we'll get some sense of the complications and the clinical conditions and so forth, and we'll compare those who actually go on to a SNF stay and those who don't, and to see if there are, first, any differences in their length of stay.

DR. ROWE: It would also permit you to have a better view of cost. You said you were looking at cost, but you may be looking at HCFA's cost rather than the actual

cost of the services to be provided. If you have the length of stay and you know what the hospital's cost was of the services that were provided, as opposed to just the DRG payment which would have been HCFA's cost independent of the length of stay.

MS. WALTER: We're interested in the cost, obviously, on the SNF side. But again, in the absence of anything better we have to rely on the APR-DRGs and the DRGs to give us some --

DR. ROWE: No, I think it's great. I just wanted to make sure you had it on the hospital side as well as the SNF side.

DR. NEWHOUSE: I still have a problem though. I have two problems actually and one of them relates to this, which is -- ultimately they both relate to the amount of information you have to interpret these changes. First, we think at least that people are behaving differently now, and we just talked about staying longer in the hospital for the intense cases. Some people may well be going directly to home health instead of going to the SNF at all. So that's kind of point one. So there's different -- different people

are in SNFs before and after, potentially.

Then two is, I presume you're just going to have administrative data on these people. I'm worried about the clinical panel -- and in some sense, the clinicians should speak to this rather than me. But I would have been very surprised if the clinicians could interpret a change in services, given the information you're going to have available, to them from administrative data. Now maybe you've got more than administrative data.

MS. WALTER: I don't know what you mean by administrative data.

DR. NEWHOUSE: Claims data.

MS. WALTER: That's all we have. This analysis --

DR. NEWHOUSE: That's what I thought. So I would think it would be extraordinarily hard to say whether a reduction in services, particularly given what goes on in -- you don't really know what goes on in the hospital, do you, with respect to therapies from the claims data?

MS. WALTER: We're going to be looking at, pulling up all of the files, the claims, the DME files, the inpatient files, the SNF files.

DR. NEWHOUSE: Does the inpatient file have a therapist's visit on it?

MS. WALTER: We're not so interested -- on the inpatient side we're just interested in knowing what the --

DR. NEWHOUSE: The non-therapy ancillaries. Well, all right. The drugs can --

MS. WALTER: We can get some of that information from the claims data.

DR. NEWHOUSE: You can?

MS. WALTER: There's the ICD-9, the CPT, HCPC codes and so forth.

DR. LAVE: -- pharmacy --

DR. NEWHOUSE: Pharmacy from the claims?

DR. LAVE: Some claims come in with six or seven big payment --

DR. NEWHOUSE: Let me just say, how in the world is a clinician going to say anything about outcomes? They're not going to know what the drugs were or what --

DR. ROWE: I think there is -- I don't know if any of us are really clinicians. I'm not sure -- Ted is dialyzing and I'm not sure Dr. Loop is still operating on

people's hearts and whatever. But if we're supposedly the clinicians here I guess some of us can comment.

DR. NEWHOUSE: Everything's relative. That's what we teach our students.

DR. ROWE: Right, exactly. I think there are a couple of problems here. Another, in addition, methodological problem is that if you're doing a longitudinal study here and you're looking for change over time, one of the things that I think we're seeing nationally -- we're certainly seeing locally in New York but I think we're seeing nationally, is case mix index is declining. There is this reduction in case mix index, kind of a downcoding as some people -- Secretary Shalala feels it may be related to the fraud and abuse concerns and that people are more cautious.

Whatever it is, it's a significant reduction in case mix index, and that is a secular effect that is going on at the same time that you're trying to do this longitudinal study and you're trying to match patients, you're going to have that confounding. So I just want to throw that in. You may be able to correct for that.

I think the easiest way to do this, Deborah, from what I've heard is to try to take a set of patients who are pretty homogeneous, like patients who had a hip fracture, or patients who had a CABG, or one DRG in which it's pretty common and there are a large number of patients and there's not a tremendous amount of variability around that and follow them, and you might be able to --

DR. NEWHOUSE: Isn't there variability within those DRGs?

DR. ROWE: I know. I'm just trying to make it a little easier than what you had, which is 24 different things going in different directions at the same time. It reduces the variance a little bit so that you can get a handle on it.

MS. WALTER: The 24 DRGs -- and I appreciate that because I know we've had a lot of internal discussions about how wide the scope is -- I think was mainly to focus on, in terms of the case mix and changes. But I agree with you that when we get to the last two questions, we absolutely do need to limit our analysis to five different kinds of patient types that based on the expertise of the clinical

panel think are the most appropriate for the reasons that you mentioned, and to look at them.

Again, this is baseline information just to get a taste of the lay of the land, and part of the clinical panel's role will be to say whether or not that they can help interpret this. It may just be that, here it is. Yes, we see a change but we'll need more data or more time to figure out whether or not we can make any kinds of solid interpretations from that. But I think for information, for baseline's sake, is important.

DR. WILENSKY: I think the study is important.

DR. NEWHOUSE: If you could do it it would be very important.

DR. WILENSKY: The only question is how well we'll actually be able to discern the changes that are resulting from the prospective payment, because there's an enormous amount of change going on. The decline in case mix is -- I mean, that's no small --

DR. LAVE: Yes, but that should happen in both hospitals. I mean, unless there's a -- if these hospitals are distributed across the country --

DR. ROWE: Sure, if you're doing it cross-sectionally comparing hospital A to B, yes. But if you're doing it longitudinally --

DR. LAVE: No, but I thought they were going to take these two panels that were going through sort of looking --

DR. ROWE: I thought they were going to do a before and after.

DR. NEWHOUSE: That's right.

DR. LAVE: But they're doing a comparison before and after --

DR. ROWE: Your baseline is going --

DR. LAVE: I thought comparing hospitals that were covered and hospitals that weren't.

DR. NEWHOUSE: No, this is SNF.

DR. LAVE: I was talking about the hospital. But I think the problem with the hospital decline in case mix would be okay because both sets of hospitals --

DR. ROWE: She had a slide saying that the case mix index was going to be used --

DR. LAVE: It would decrease less in the hospitals

that are referring --

DR. ROWE: I'll buy you a glass of wine later and we'll discuss it. Did I get this right? Was I right?

DR. LAVE: You're right.

DR. ROWE: Did you get that?

DR. LAVE: You're perfectly right. That's because the hospitals don't refer to specific SNFs.

DR. KEMPER: I would just like to commend you on having really laid out in a good bit of detail the analysis plan, and just really congratulate you on that. I will say, the bad news of that is by fully articulating a plan it invites a lot of comments. But in the interest of letting Jack buy Judy a glass of wine, I will give these to you separately. But I really think this is a very nice job of laying out what you're going to do.

DR. WAKEFIELD: Actually, Gail or Joe, this is a question for you, and actually I was a clinician in a nursing home both as an educator and a practitioner; different nursing homes as a matter of fact and I've got to defer back to you for the answer to this question because based on my practice experience I couldn't answer it.

The issue has been raised about looking at the data -- can you really answer these questions aside for just a second -- concern about delays in patient discharges from hospitals for high acuity patients. Here's my question to you. Would there also be a reverse concern? That is, would SNFs be incentivized with the new payment system to discharge back to a hospital a high acuity patient that ordinarily would have been cared for, continually cared for in that SNF but because of the payments, payment changes, they may prefer to move that patient back into the hospital for care?

DR. WILENSKY: I guess we could look to see whether there's a readmission issue. That would be able to be seen from common working file information.

MS. RAPHAEL: But there's always been a high percentage of cases going from the nursing homes back to the hospitals.

DR. WAKEFIELD: Any difference, that's my question. Is there any difference --

MS. RAPHAEL: I don't know, but I know that it has always been fairly high. I think in my state it's like 40

percent of the patients within a six-month period go back to the hospital.

DR. WAKEFIELD: So is it 60 percent now?

MS. RAPHAEL: I don't know.

DR. WAKEFIELD: Is it 40? That's my question.

DR. ROWE: And it's particularly common in certain diagnoses, the most common of which is congestive heart failure.

DR. WAKEFIELD: Yes, and I'm wondering about the relationship to the payment changes. So maybe not so much what has been the case historically, but are they incentivized now to rehospitalize higher acuity patients? That's my question.

DR. WILENSKY: I guess to the extent that you think that you can look at this --

DR. NEWHOUSE: Certain kinds of high acuity patients.

MR. MacBAIN: It was explained to me that under the RUG system -- this goes back a couple years ago now, the set of RUGs as proposed -- patients for whom the cost of outside services, services provided by agencies outside the

SNFs, such as ambulance or mobile x-ray or whatever, would exceed the RUG per diem payment. For those patients there's a very clear incentive either not to admit them or to send them back to the hospital.

DR. NEWHOUSE: That's right. That's the subset.

DR. WILENSKY: I think to the extent we can look at this issue empirically that would be another impact of the prospective payment. I agree with Peter's comment, this laid out your workplan in some detail on a very difficult subject so it does invite a lot more comment. As we go along, I'm sure you'll have more.

DR. LAVE: But we want to incentivize them somehow to do it, so how do we do that?

DR. NEWHOUSE: Incentive them to do what?

DR. LAVE: To give details.

DR. WILENSKY: We provide them with compliments about how much we appreciate the detailed workplan.

Let me turn to the public. This has been a long day on a diverse set of issues. If there are any public comments that people would like to make from any of the topics we've covered today, this is the appropriate time.

Identify yourself and please --

MS. ZOLLER: I'm Caroline Zoller with the American Medical Rehabilitation Providers Association. I'll just try to do this in one sentence because I know you want to run. We are looking at the MDS-PAC in terms of whether or not it would collect the information necessary to categorize patients into the FRGs, since HCFA has made that decision. We'll be back to the staff and to the Commission before the next meeting on that point.

DR. WILENSKY: Thank you.

MR. CALMAN: I will be almost as brief. I'm Ed Calman, general counsel, the National Association of Long Term Hospitals. I'd like to make just a few points.

We sponsored the research that developed the proposed PPS system that some of you have seen, and in the course of that we compared the weights of DRGs in short term hospitals to long term hospitals. We had 70,000 cases, and the weights are different. Some of them are higher and some of them are lower. So that shows different resource use and may be helpful.

Secondly, long term hospitals really act as

referral centers. You need a critical mass of patients to do a number of programs, like ventilator weaning programs, wound care programs for difficult patients, and other kinds of cases. The concern about developing a payment system where any hospital can have the payment rate is that some of these hospitals that are 200, 300 beds do not have the critical mass of patients. So therefore, if they're incentivized to keep the patients, the referrals will not come to the referral center and those programs will be diminished.

What's worse, a lot of these cases are crossover cases. They exhaust Part A. You really can't look at them, unless you look at them when they're Part B after exhausting Part A, to understand what they are.

Another issue I would raise and then I'll leave, is that if you develop a high weight DRG, whether it's taking the current DRGs and reweighting them, which we've done, and then you give that to an acute care hospital, or you develop a few more, they all have to be high weight because of the length of stay and the resource use. You would then encourage upcoding to those high weight DRGs in

hospitals where the cost base is higher.

Finally, a lot of these costs in stays have been taken out of PPS because of the recalibration process as long term hospitals develop. I would like to make sure as you go about your workplan that you do consider the crossovers, because some of these cases come in on day 90 or day 80 of this illness have a 30 or 40-day length of stay, and in order to truly understand the institution you have to follow them after they leave Part A and they're still Medicare beneficiaries because they're Part B.

Thank you very much.

DR. WILENSKY: Thank you.

MR. GRAEFE: Thank you, Gail. Fred Graefe of Baker and Hostetler on behalf of Baxter. As I've mentioned to you before, we're in favor of removing the statutory bar in Section 1876 to allow plans to treat Medicare beneficiaries who have ESRD. I'd like to commend the Commission and Nancy for a very comprehensive and ambitious workplan on ESRD, but one comment on it. The plan as presented would apply quality measures, performance outcomes only to plans.

If that were to be your recommendation, at the same time recommending that the bar be removed, then the law of unintended consequences would kick in, in my judgment, and plans then would not take Medicare beneficiaries because these quality measures, which are very necessary -- it's a very fragile and brittle population. My recommendation to you is that your quality measures, which you have already clearly articulated very well in last year's report, should apply equally and in full force to both plans and to fee-for-service providers.

Thank you very much.

DR. WILENSKY: I didn't realize they didn't. We'll make sure -- I don't think it was anybody's intent to have a differential set of indicators.

MR. GRAEFE: Thank you.

MS. HOLDER: Hello, I'm Elma Holder with the National Citizens Coalition for Nursing Home Reform. I was here this morning for the presentation from JCAHO and listened to that panel. I wanted to tell you that from a consumer perspective that raised a lot of concerns for us because I feel like a lot of the issues that are of serious

concern to consumers related to deeming and regulation versus accreditation were glossed over this morning.

So I would ask you -- I understand that you did have a panel of consumers related to home health care and I would ask that you have a panel of consumers representing nursing home interests to come and appear before you. Not only were the issues of deeming and accreditation and those issues raised, but the issue of staffing was raised as well and that's a very serious issue to us and we have some very vivid, lengthy experience this past year on the staffing issue with people around the country with what's happening on that, and I think it's valuable information that we should have an opportunity to present to you.

Thank you.

DR. ROWE: I recommend we accept the recommendations of anyone from the public who is the recipient of the Gustav Lienhart award which was bestowed upon her on Monday at the Institute of Medicine annual meeting.

[Applause.]

DR. WILENSKY: We are adjourned until 9:00

tomorrow morning.

[Whereupon, at 5:42 p.m., the meeting was recessed, to reconvene at 9:00 a.m., Friday, October 15, 1999.]